Certification of Completion of the Informed Consent

IRB #

Title:

I have discussed the "Informed Consent for Participation in Research Activities" in its entirety for the above referenced research study, with the research participant listed below (or the research participant's legally authorized representative). During the review of the consent form, the possible benefits, risks and discomforts involved in his/her participation on the study, as well as potential alternatives were reviewed.

The research participant has been encouraged to ask questions, and all questions asked by the participant have been answered. The research participant affirmed that he/she has received all information that he/she desires at this time, and a copy of the signed consent form has been provided to the participant.

| PRINTED NAME of Person Obtaining Informed (Consenter) | SIGNATURE | TITLE | DATE | TIME |
|---|---|---|---|---|
| | | | | |

Principal Investigator: Virginia Sun, PhD, RN
Department/Division: Population Sciences, Division of Nursing Research and Education
Telephone number: 626-218-3122

City of Hope

**INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES**

**IRB#19556- Self-Management to Optimize Survivorship Care and Outcomes in Lung and Colorectal Cancers**

## KEY INFORMATION

You are invited to participate in a research study. The purpose of this research study is to test if an intervention, the Self-Management Survivorship Care program, can give you timely information about your follow-up care after cancer treatment, improve your knowledge and confidence about your follow-up care, improve the communication with your cancer care and primary care doctors, and improve your quality of life after cancer treatment.

The information we learn by doing this research study may help you gain additional information and/or support on your follow-up care after finishing cancer treatments. Potential benefit to others may result from the knowledge gained from your taking part in this research study.

Participants in this study are individuals with a history of lung or colorectal cancer who finished all cancer treatments four to six months ago. Patients with lung cancer that are treated with immunotherapies and/or targeted therapies and patients with colorectal cancer that spread to the liver can also participate. Your participation is expected to last about 8 months.

The major risks associated with the study are the time and effort to take part in the program and including answering study-related questions. We do not expect you to experience any physical, financial, or legal risk as a result of taking part in this study. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. The possible risks and discomforts of participation are:

**Questionnaires**: You may become tired from the amount of time needed to fill out the questionnaires. The questionnaires will focus on life issues, such as worry and sadness, which could cause you to become emotionally upset. If this occurs, you will be referred to your doctor to determine how best to handle the concerns and issues. Support and counseling will be available from social workers as needed.

You do not have to join this research study. If you are interested in learning more about this study, please continue to read below.

I. **PURPOSE OF THIS RESEARCH STUDY**: You have been asked to participate in this research study because you are four months out after completing all cancer treatments for lung or colorectal cancer, being treated with immunotherapies or targeted therapies, or have colorectal cancer that spread to the liver. The purpose of this study is to look at how the Self-Management Survivorship Care program can improve your knowledge and confidence about your follow-up care, improve the communication with your cancer care and primary care doctors, and improve your quality of life after cancer treatment. Your participation in this study is expected to last about 8 months.

A total of 414 patients will take part in this study.

II. **BACKGROUND**: After completing treatments for lung or colorectal cancer, patients may continue to experience many problems from treatment. Follow-up care after treatment also can be hard to manage. Coaching you on your follow-up care after cancer treatments may improve your knowledge and confidence about your follow-up care, improve the communication with your cancer care and primary care doctors, and improve your quality of life after cancer treatment.

III. **WHAT WILL BE DONE**: If you agree to participate, you will be asked to do the following:

**Questionnaires:**

You will be asked to complete a set of questionnaires when you agree to participate in the study. It will take up to 45 minutes to answer the questions about your knowledge and confidence about your follow-up care, the quality of the communication with your doctors, and your quality of life). You will fill out the questionnaires in-person, by telephone, or through the internet. If you choose to fill out internet questionnaires, we will ask you to provide us with an email address. You will be given a special link to the questionnaires through an email sent to your email inbox.

You will be randomized (assigned by chance, similar to flipping a coin) to one of two groups: an intervention group where you will receive the self-management program, or a control group where you will receive information from the National Cancer Institute on cancer survivorship. The reason for the two groups is to make sure that any improvements in quality of life are in fact due to the program and not to other things. You will have an equal chance of being assigned to either group.

**Self-Management Survivorship Care Program:**

If you are assigned to the Intervention Group, you will receive the Self-Management program. The program will be given in 8 sessions by a trained nurse, and each session will last about 40 to 60 minutes. Sessions 1-5 will be given to you over a 4-month period. Before Session #1, the Intervention Nurse will work with your doctors to put together your follow-up plan. The Intervention Nurse will use the questionnaire answers that you shared with us to make sure your follow-up plan meets your needs after cancer treatments.

The program will be delivered using Hope Virtual or Teams Meeting, videoconferencing system through the internet. The study staff will work with you to schedule the sessions at a time and date that is convenient for you. You will receive reminder calls from the study staff one day prior to each of the telehealth sessions. The study staff will review and test the Hope Virtual or

Teams Meeting system with you at least 3 days before Session #1 to make sure that you understand how to get on the video calls.

If you have a home computer or tablet, you may use them to participate in the telehealth sessions. If you do not have a computer or tablet, you will be offered the option of borrowing a study ipad. If you choose to borrow a tablet, you will need to sign an equipment loan agreement. You will not be responsible financially to pay for any damaged or lost computer device or tablet.

In Session #1, the Intervention Nurse will share the follow-up plan with you, and ask you for input. The nurse will ask you if you have a family doctor who you see outside of City of Hope. If you don't have one, the Intervention Nurse will work with you and your doctor and find a family doctor to help with your follow-up care. Both your family doctor and your cancer doctor will be invited to participate in the study.
In Session #2, The Intervention Nurse will review your follow-up plan with you and give you a manual that includes all the program information. The Nurse will talk about some possible physical and emotional well-being concerns that are common after cancer treatments. The Nurse will review community resources that may help with your needs after treatment. The Nurse will help you set goals that you would like to meet to keep you physically and emotionally well after treatment.
In Session #3, The Intervention Nurse will review your follow-up plan with you and talk about some possible social and spiritual concerns that are common after cancer treatments. The Nurse will review community resources that may help with your social and spiritual needs after treatment. The Nurse will help you set goals that you would like to meet to keep you socially and spiritually well after treatment.

In Session #4, The Intervention Nurse will review your follow-up plan with you and talk about how to stay physically active after treatment. The Nurse will review community resources that may help with your physical activity after treatment. The Nurse will help you find a goal of physical activity after treatment.

In Session #5, The Intervention Nurse will review your follow-up plan with you and talk about healthy living after cancer treatment. The Nurse will review community resources that may help with your healthy living after treatment; this includes eating a healthy diet and staying physically active. The Nurse will help you find a goal on your healthy living after treatment, and he/she will communicate with your family doctor on your follow-up plan. Your family doctor and cancer doctor will be given a one-page summary on your care.

Three additional sessions will be given to you on a monthly basis after Session #5. In these sessions, the Intervention Nurse will review any information from the last 5 sessions, review your goals, and continue to communicate with your family doctor. After you complete the additional sessions, your family doctor and cancer doctor will be given a one-page summary on your care.

If you are assigned to the Control Group, you will receive 1) five telehealth sessions (delivered by the Attention Control nurse or clinical research staff) to answer your questions about the National Cancer Institute's (NCI) "Facing Forward: Life After Cancer Treatments" handbook

(for patients with stage I-III disease) or the ASCO Lung or Colorectal handbooks (for patients with stage IV disease); and 2) additional monthly telehealth sessions during months 5-7 to answer questions about the NCI or ASCO handbook.

**Planned Follow-Up:**
Additional questionnaires will be collected at the following time points: at 4 months after finishing the study activities, and again at 8 months. The questionnaires are the same ones that you completed at the beginning of the study.

You will also be asked to answer 3 open-ended questions on the impact of the COVID-19 pandemic on your cancer care, work situation (if you are working), your income, your finances, your housing, and your physical/emotional well-being. You will be asked to answer the questions at baseline only. You can answer the questions by email, by mail, or by giving your answers verbally to research staff. If you are giving your answers verbally to the research staff, your answers will be audio-recorded for data analysis purposes. The audio recordings will be transcribed into written documents for analysis. The recordings will be destroyed after data analysis is completed.

You will receive $50 at completion of baseline questionnaires, $50 at completion of questionnaires at 4 months, and an additional $50 at completion of questionnaires at 8 months. The total is $150 for participation in the study.

If you are assigned to the Intervention Group, at the 8-month follow-up, we will also ask you to complete a short interview that lasts about 30 minutes. During the interview we will ask you to tell us about your experience with the intervention program and your satisfaction with the program. The interview will be audio-recorded.

**How will my information be protected:** This research will be conducted in compliance with federal and state of California requirements relating to protected health information (PHI). This information will be contained in a password protected database. Questionnaires will not contain PHI information.

All future data analysis will be performed on de-identified data. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

For interview data: The digital audio interview data will be downloaded into an encrypted and secure City of Hope network drive and deleted from the recorder. Digital audio interview data will be coded and study identification numbers applied. All personal identifiers will be removed. The original, de-identified hard copy transcriptions of the audio data will be stored in a locked office in the Population Sciences building in the Division of Nursing Research and Education, room 184.

IV. **POSSIBLE BENEFITS**: You may benefit from participation in this study if you gain additional information and/or support on follow-up care after treatments. Potential benefit to others may result from the knowledge gained from your participation in this research study.

V. **POSSIBLE RISKS**: The risks and discomforts of this study include time and effort to take part in the program and including answering study-related questionnaires. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. The possible risks and discomforts of participation are:

**Questionnaires**: You may become tired from the amount of time needed to fill out the questionnaires. The questionnaires will focus on life issues that could cause you to become emotionally upset. If this occurs, you will be referred to your physician to determine how best to handle the concerns and issues. Support and counseling will be available from social workers and psychologists as needed.

VI. **ALTERNATIVES TO PARTICIPATION**: You have been informed that alternatives to participation include choosing not to participate. The researcher has discussed alternatives to participation with you. Choosing not to participate will not interfere with any future treatment at or any relationship with City of Hope.

VII. **CONFIDENTIALITY OF INFORMATION**: Any information learned from this study in which you might be identified will be confidential and disclosed only with your permission. Every effort will be made to keep any information collected about you confidential. However, it is impossible to guarantee that information about you will not be mistakenly released. If, despite our best efforts, identifying information about you is released, it could negatively impact you or your family members. This risk is small.

By signing this form, however, you allow the researchers to make your information available to City of Hope Institutional Review Board (IRB) Office, the Cancer Protocol Review and Monitoring Committee (CPRMC), the Office for Human Research Protections (OHRP), the National Cancer Institute (NCI), Vital Research, and other regulatory agencies as required by law. If information learned from this study is published, you will not be identified by name.

**Certificate of Confidentiality**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The Certificate protects against the release of information, documents or biospecimens that may identify you that was collected during the period the Certificate is in effect to individuals not connected with the research. For example, the researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you choose to voluntarily disclose the protected information under certain circumstances (for example, if you request the release of information in writing), the Certificate does not protect against that voluntary disclosure. Additionally, the Certificate of

Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, for other scientific research, as allowed by federal regulations protecting research subjects, or for your medical treatment.

**Future Use of Research Information**

In the future, the information that has been collected for this study will be de-identified, which means any information that could be used to identify you will be removed from the information. The de-identified information may be used for future research studies or shared with other researchers. You will not be informed of or asked to consent to these future research activities.

VIII. **OFFER TO ANSWER QUESTIONS**: The principal investigator, Dr. Virginia Sun or a colleague, Dr. Marwan Fakih, has offered to and has answered any and all questions regarding your participation in this research study. If you have any further questions, you can contact Dr. Virginia Sun at (626) 256-HOPE (4673) ext. 83122.

IX. **SPONSOR OF THIS RESEARCH**: The National Cancer Institute is the sponsor of this research study.

X. **COST TO THE RESEARCH PARTICIPANT FOR PARTICIPATION**: Neither you nor your insurance carrier will be charged for your participation in this study.

XI. **VOLUNTARY PARTICIPATION WITH RIGHT OF REFUSAL**: You have been informed that your participation in this research study is voluntary. You are free to withdraw your consent for participation in this study without any loss of benefits, penalty, or interference with any future treatment at, or any relationship with City of Hope.

XII. **IRB REVIEW AND IMPARTIAL THIRD PARTY**: This study has been reviewed and approved by the Institutional Review Board (IRB). A representative of that Board, from the Office of Human Research Subjects Protection, is available to discuss the review process or your rights as a research subject. The telephone number of the Office of Human Research Subjects Protection is (626) 256-HOPE (4673) ext. 62700.

XIII. **FINDINGS RELATING TO WILLINGNESS TO CONTINUE PARTICIPATION**: The person consenting you to this study has explained to you that you will be informed of any significant new findings related to this study which might affect your willingness to continue to participate.

## EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FOR PSYCHOSOCIAL STUDIES

The rights below are the rights of every person who is asked to be in a research study. As a research subject in a psychosocial or quality of life study, you have the following rights:

1. To be told what the research study is trying to find out,

2. To be told what will happen to you and whether any of the study procedures to be used are different from what would be used in standard practice,

3. To be told about the risks, side effects, or discomforts of the things that will happen to you as part of the research study,

4. To be told if you can expect any benefit from participating in the research study, and, if so, what the benefit might be,

5. To be told of the other choices you have and how they may be better or worse than being in the research study,

6. To be allowed to ask any questions concerning the research study, both before agreeing to be in the study and during the course of the study,

7. To be told what support or treatment is available if any complications arise,

8. To refuse to participate in the research study or to change your mind about participation after the study is started. To be informed that this decision will not affect your right to receive the care you would receive if you were not in the study,

9. To receive a copy of the signed and dated research study consent form,

10. To be free of pressure when considering whether you wish to agree to be in the research study.

**SIGNATURE FOR CONSENT**: By signing this consent form, you are making a decision to participate in this research study. Your signature on this informed consent form indicates that you:

1. Have read and understood the information in this form.
2. Have had the information in this form explained to you.
3. Have had a chance to ask questions and these questions were answered to your satisfaction.
4. Have been informed that you will receive a copy of this signed consent form, which includes the "Experimental Subject's Bill of Rights."

I hereby agree to be a research participant in this research study:

_____ _____ _____
Research Participant's Signature Date Time
(For paper consent only, then the date and time must be in research participant's handwriting)

_____
Print Research Participant's Name

**INDIVIDUAL OBTAINING CONSENT SIGNATURE**

_____ _____ _____
Signature of Individual Obtaining Consent Date Time

_____
Print Name of Individual Obtaining Consent

**IRB# 19556:** Self-Management to Optimize Survivorship Care and Outcomes in Lung and Colorectal Cancers

## AUTHORIZATION TO USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI) FOR PURPOSES OF THIS STUDY:

**I.** **Purpose of this Authorization**: The information about your health is something that is protected by law and cannot, except for certain purposes, be disclosed (shared) without your permission. As part of this research, you are agreeing to allow City of Hope, its affiliated research doctors, healthcare providers, and physician network to use and share with others your protected health information ("PHI"), as needed for the research. If you agree to participate in the study named above (called the "Study"), you must sign this authorization in addition to the Study Consent Form.

**II.** **The Information About You that is Covered By this Authorization**: PHI refers to information that we maintain about you that identifies you and includes the information contained in your medical record. Your medical record consists of information related to your health and the treatment we provide to you, such as your medical history, the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures. If you sign this authorization, you are allowing City of Hope and the individuals indicated below to use and share any PHI we maintain about you that is required for your participation in the Study.

**III.** **Purposes for Uses and Sharing of your PHI; Who Will Use, Share and Receive your PHI**: Your PHI will be used and shared with others for the purpose of doing this research as described in the Study Consent Form. Your PHI will also be used to keep the research sponsor informed about this Study, for reporting to those individuals and authorities responsible for overseeing our research activities to make sure that the activities are properly conducted, and to report to regulatory agencies as required by the Study.

The people authorized to use and share your PHI for purposes of the Study include the Principal Investigator and the research staff supporting the Study; your City of Hope physicians and the health care team; the Health Information Management Services Department (i.e., Medical Records Department); and affiliated research doctors and other medical centers participating in the research, if applicable. This also includes any agents or contractors used by these individuals or groups for

purposes of conducting or managing this Study. At the City of Hope, the Institutional Review Board ("IRB"), and other City of Hope research regulatory committees will have access to your PHI as necessary to monitor research.

You are also allowing your PHI to be shared with the Office for Human Research Protections ("OHRP") and with any person or agency as required by law. In addition, certain other regulatory agencies, including the Food and Drug Administration ("FDA"), and the National Cancer Institute ("NCI") will have access to your PHI.

This authorization will allow us to use and share your PHI for the Study. No other additional uses and disclosures other than for the purposes of the Study is included in this authorization. City of Hope's Notice of Privacy Practices will continue to protect your non-Study information. If necessary, another separate permission will be obtained from you for any non-Study uses or sharing of your PHI.

**IV.** **Expiration of this Authorization**: This authorization to use and share your PHI will expire twenty-five (25) years from the date that you sign this authorization.

**V.** **Further Sharing of Your PHI**: Your privacy is important and this is the reason for having rules which control who can use or see your PHI. City of Hope maintains control over your PHI at present, but once we share this information with a third party (for example, an individual or agency outside of the City of Hope), then it is no longer possible to maintain the same level of protection. The persons outside our control may not be governed by federal or state privacy laws and it is possible that they could share your PHI with others for whom you have not given permission.

The information from this Study may be published in scientific journals or presented at scientific meetings but your identity will be kept confidential.

**VI.** **<u>Your Rights Under this Authorization</u>**: You may cancel this permission to use and share your PHI at any time by contacting City of Hope's Privacy Officer at (626) 256-HOPE (4673) ext. 64025. You should ask for the form, Revocation (Cancellation) of Authorization for Use of Protected Health Information for Research. Fill this form out and return it as the form instructs. Your cancellation begins when the Health Information Management Department of City of Hope receives this form. If you cancel this authorization to use and share your PHI, you will no longer be able to participate in the Study. This is because the research under this Study cannot be conducted without your PHI.

Once you cancel your permission to use and share your PHI, the researchers and others involved in conducting the Study will no longer be able to use or share your PHI for this research. PHI already used and shared up to this point as part of this Study will continue to be used for purposes of this research. This means that any uses of your PHI and any PHI shared about you by City of Hope prior to receiving your cancellation (revocation) form cannot be taken back. While no further PHI about you will be shared for the Study, your PHI already shared will continue to be used in the overall Study.

**VII. <u>Signing this Authorization is Your Choice</u>:** Your ability to obtain care at the City of Hope will not be affected by your decision to sign this authorization form. You will be able to continue to receive health care at City of Hope if you choose not to sign this authorization form or if you sign this form and later cancel your permission to use and share your PHI.

If you agree to the use and sharing of your PHI, please sign below. You will be given a copy of this authorization form.

_____ _____ _____

Research Participant's Signature Date Time(For paper consent only, then the date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

**INDIVIDUAL OBTAINING CONSENT SIGNATURE**

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent