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: Laleh Melstrom, MD
Department/Division: Department of Surgery
Telephone number: 626-218-7100

City of Hope

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

COH Protocol# 20717: Perioperative Telemonitoring to Optimize Cancer Care and Outcomes

KEY INFORMATION

You are invited to participate in a research study. The purpose of this research study is to understand the usefulness of an at-home monitoring program to reduce complications during recovery after cancer surgery. Patients will use home monitoring devices to report health data (including weight, temperature, oxygen level, heart rate, and blood pressure), wear a Vivofit 4 watch to track daily steps, and use a study-provided tablet to answer questionnaires on symptoms and quality of life. The home monitoring will begin before surgery and continue for up to 30 days after hospital discharge. Nurses will monitor your data and you will be randomly assigned to either the group where nurses call you when there are abnormal values or the standard group where the data are collected and stored.

Participation is expected to last 2 to 3 months.

The information we learn from this research study may result in you gaining additional information and/or support during your recovery from surgery. There may be a potential benefit to others recovering from surgery from what we learn from this study.

The major risks associated with the study are your time and effort to take part in the at-home monitoring program and to answer the study-related questionnaires. You may become tired from the 5-7 minutes 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.

There is no cost for you to participate. We do not expect you to experience any physical or legal risk from taking part in this study. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

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. **<u>PURPOSE OF THIS RESEARCH STUDY</u>**: You have been asked to participate in this research study because you are scheduled for surgery for your cancer. The purpose of this study is to see

whether an at-home monitoring program that collects health, symptoms, and quality of life data in real-time can be included as part of the care of surgery patients in order to provide better recovery.

Your participation in this study is expected to last 2 to 3 months. About 160 people will take part in this study.

II. **BACKGROUND**: Patient-generated health data (weight, temperature, oxygen level, heart rate, blood pressure, daily steps, symptoms, quality of life) using at-home monitoring devices (thermometer, a pulse oximeter, a digital scale and a vivofit 4 watch) and smart device applications are used more and more to measure value and quality in cancer care. We have previously shown that the number of daily steps after surgery is related to potential complications after surgery (patients who took more steps had fewer complications). However, measuring patient-generated health data is not currently part of standard care following cancer surgery. Therefore, we do not know whether the monitoring and data can improve the care of patients after hospital discharge from surgery.

III. **WHAT WILL BE DONE**: If you choose to participate, you will be randomly assigned (like flipping a coin) to either the nurse-monitoring group or to the standard care group. In the monitoring group, the nurse will check your data daily and if there are abnormal values (such as a fever or low blood pressure), they will reach out to you. In the standard care group, we will collect your data but you will be expected to communicate with your physician and medical team per the usual instructions (calling the City of Hope triage line per your discharge instructions). If you agree to join the study, you will be asked to complete three (3) online questionnaires about your symptoms and quality of life. These threeonline questionnaires are EQ-5D-5L, Global Health Survey, and MDASI. You will be asked to complete these three online questionnaires up to 7 days before surgery, before being discharged from the hospital after surgery, and at Day 2, Day 7, Day 14, and Day 30 after discharge. You will be asked to complete the online questionnaires by using a study tablet that will be provided to you for use while you are on the study or on the Aetonix app that can be loaded on your phone. You will also be asked to fill out a short one-time sociodemographic online questionnaire provided to you before your surgery date. The questionnaires will take you about 7-10 minutes to complete. If a study tablet is used, it will need to be returned to the study team after you have completed the study and the team will provide the posting packaging at no cost to you. If the device is lost, you will not be responsible for the cost of the replacement.

Questionnaires:

- EQ-5D-5L - This questionnaire has five quality of life topics: movement, self-care, usual activities, pain/discomfort, and anxiety/depression.

- MD Anderson Symptom Inventory (MDASI) - This is a brief measure of 13 common cancer-related symptoms with severity of each rated on a 10-point scale. In addition there are questions about how the symptoms interferes with participants' lives.

- Global Health Survey – This survey contains 4 multiple choice questions relating to your

mental and physical well-being.

- Sociodemographic and Health Status – This survey is 13 questions in multiple choice format relating to your sociodemographic and health background.

You will be given a Vivofit 4 wristwatch to wear for 30 days after hospital discharge. The watch collects and tracks the number of daily steps that you take. The study staff will set up the watch for you, and will teach you how to use the watch during the study.

You also will receive a package with at-home monitoring devices. The devices are provided by a company called Aetonix. The devices are cleared by the United States Food and Drug Administration (FDA) to be used for home monitoring of patients. The package includes a weight scale, thermometer, blood pressure cuff, and devices to measure your heart rate and oxygen level. Instructions on how to use the devices will be included in the package. The study staff will also teach you how to use the devices. You will be asked to use the devices at home to measure your weight, temperature, blood pressure (BP), heart rate, and oxygen level one time before your scheduled surgery and then at Day 2, Day 7, Day, 14, and Day 30 after you go home from the hospital. At each of these days, you will be required to measure your weight, temperature, blood pressure (BP), heart rate, and oxygen level once in the morning but you will have the option of taking these measurements again in the afternoon, should you choose to. This will take 5-7 minutes to complete.

The study will begin before surgery (at least 7 days before surgery for baseline measurements), and will continue after hospital discharge for at least 14 days and up to 30 days.

All patient data captured by the devices and study tablet or the Aetonix app will be streamed (via wifi or cellular data network) to a clinical dashboard. The devices do not store any personal data. These data will be collected and sent in a de-identified manner where participant identity is known only to the principal investigator and the clinical research nurse. We will also collect information from your medical record, including your surgery and clinical information, such as diagnosis, and any other treatments you have received.

Lastly, at the end of the study, we will ask you to complete a satisfaction questionnaire that covers the difficulty and timing of using the devices. This will take 5 to 7 minutes. Additionally, we will ask you questions through a short interview about your use of these devices and your participation in the study. This will take 5 to 7 minutes. The interview will be audio-recorded so the study team can use the information that you provide to improve care. To protect your privacy, your name will not be included when the data are analyzed, and the audio recordings will be erased once the data is analyzed. At the end of the study, you may keep the Vivofit 4 wristwatch if you like it. All home monitoring devices and loaned study tablet will need to be returned.

Each time after you complete questions about your quality of life and symptoms and use your devices, a trained nurse who works with your surgeon will monitor your data. If you are in the nurse intervention arm and an issue is observed from these data, the trained nurse will be alerted

in real-time, and s/he will contact you either through a text message or by telephone. The nurse will ask you about your symptoms and provide any additional education and support when necessary. When necessary, s/he will work with your surgeon on a treatment plan for your symptoms and other physical needs. If you're in the standard care group without nurse intervention, you will reach out to your physician team following the routine instructions given to you at discharge.

Study Calendar:

	Up to 7 days before surgery	**At Discharge**	**Post discharge 2**	**Post discharge 7**	**Post discharge 14**	**Post discharge 30**
Steps (Vivofit)	Throughout study----------→					
EQ-5D-5L, MDASI, Global Health Questionnaires (5-7 min)	**X**	**X**	**X**	**X**	**X**	**X**
Sociodemographic & Health Questionnaire (2-3 min)	**X**					
Temperature, BP, Weight, Pulse Oximetry (5-7 min)	**X**	**X**	**X**	**X**	**X**	**X**
Satisfaction (5-7 min)						**X (post discharge d30)**
Exit Interview (5-7 min)						**X**

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. Surveys administered to the subjects will not contain PHI information.

All future data analysis will be performed on data that is not linked to any identifiabile information. 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.

IV. **POSSIBLE BENEFITS**: Your active involvement in your care may help reduce complications by identifying issues early. 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 the time and effort to conduct the telemonitoring and to answer the questionnaires. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Loss of confidentiality is a risk. 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 questionnaire 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.

Vivofit 4/Study Tablet: Although we do not expect this to happen, you may experience an allergic reaction to the Vivofit 4 or loaned study tablet. Symptoms may include an itchy rash, or redness or changes to areas where your skin touches the device. If you experience these symptoms, please let the study research staff know. The research staff will contact your surgical team and a treatment plan.

VI. **ALTERNATIVES TO PARTICIPATION**: Your alternative is to choose not to participate in this study. 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), 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 Department of Health and Human Services (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.

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.

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. Laleh Melstrom, or a collaborator, Dr. Virginia Sun, 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. Laleh Melstrom at 626-218-7100.

IX. **SPONSOR OF THIS RESEARCH**: City of Hope is the sponsor of this research study.

X. **ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?**
You will receive a total of $75 in gift cards for taking part in this study ($25 each for completion of the day 7, 14 and 30 assessments).

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

XII. **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.

XIII. **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.

XIV. **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

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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. **Your Rights Under this Authorization**: 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