ADULT INFORMED CONSENT

COH Protocol #20096
TITLE: Technology-Enabled Activation of Skin Cancer Screening for Hematopoietic Cell Transplantation Survivors and their Primary Care Providers (TEACH)
Protocol version date: 09/14/2020

PRINCIPAL INVESTIGATOR: Saro Armenian, DO, MPH

DAY TIME TELEPHONE NUMBER FROM THE HOURS OF 8:00 AM TO 5:00 PM: DR. ARMENIAN AT (626) 218-7320

EXPERIMENTAL PARTICIPANT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study, also known as an experiment or clinical trial. As a research participant, 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 procedures to be used are different from what would be used in standard practice.
3. To be told about the discomforts, side effects and risks 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.
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 told what medical treatment is available if any complications arise.
7. 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.
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.

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INTRODUCTION

You are invited to take part in a clinical trial, a type of research study, because you had a Bone Marrow Transplant (BMT) for cancer or a similar illness. The purpose of this research is to increase rates of skin self-examinations and clinical skin examinations among BMT survivors. This will be done by providing educational and motivational information to both BMT survivors and their primary care physician (PCP) regarding the importance of skin self-examinations. This study will also look at the impact of an electronic learning teledermoscopy (TD) program to send digital images of a mole or skin concerns to a dermatologist (skin doctor) in a remote (distant) location. We hope that the TD program leads to faster follow-up care, including speedier referrals to dermatologists.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future. Please take as much time as you need to read the consent form. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

There have been significant improvements in BMT treatments, leading to a growing number of BMT survivors. However, some survivors may develop complications related to the treatment they received. Some patients may have no problems while others may develop one or more problems related to their treatment. Many of these complications may not be known for years after the treatment. That timing can be a challenge as follow-up care tends to move from the BMT doctor back to PCP during this period. In some cases, preventive measures can be taken to reduce the chances that a complication will occur and encourage early detection.

This study focuses on one complication that BMT survivors are at high risk of developing - skin cancer. The diagnosis of melanoma (a type of skin cancer) and non-melanoma skin cancer in BMT survivors is different from the general population. They occur at a younger age and are caught at a later stage, often when the cancer is in a more advanced stage. Despite the unique risk factors and higher rates of skin care among BMT survivors, most BMT survivors report that they do not

regularly perform a skin self-exam and have not received a doctor examination for skin cancer in the past year.

An early diagnosis of skin cancer is important since the cancer is usually smaller, requires less extensive treatments and has better outcomes. Therefore, teaching skin self-examination and encouraging patients to alerts their doctors to skin changes provides an important opportunity for early detection. The goal of this study is to determine the impact of a 12-month intervention focused on early detection of skin cancer and timely medical follow up. BMT survivors are educated and encouraged, alone or with their PCP education and encouragement, on the behaviors related to skin cancer screening.

About 720 people will take part in this research study.

B. WHAT IS INVOLVED IN THE STUDY?

The study staff will make sure you are eligible for this study by asking a few questions regarding your current health status and the name and contact information for your PCP.

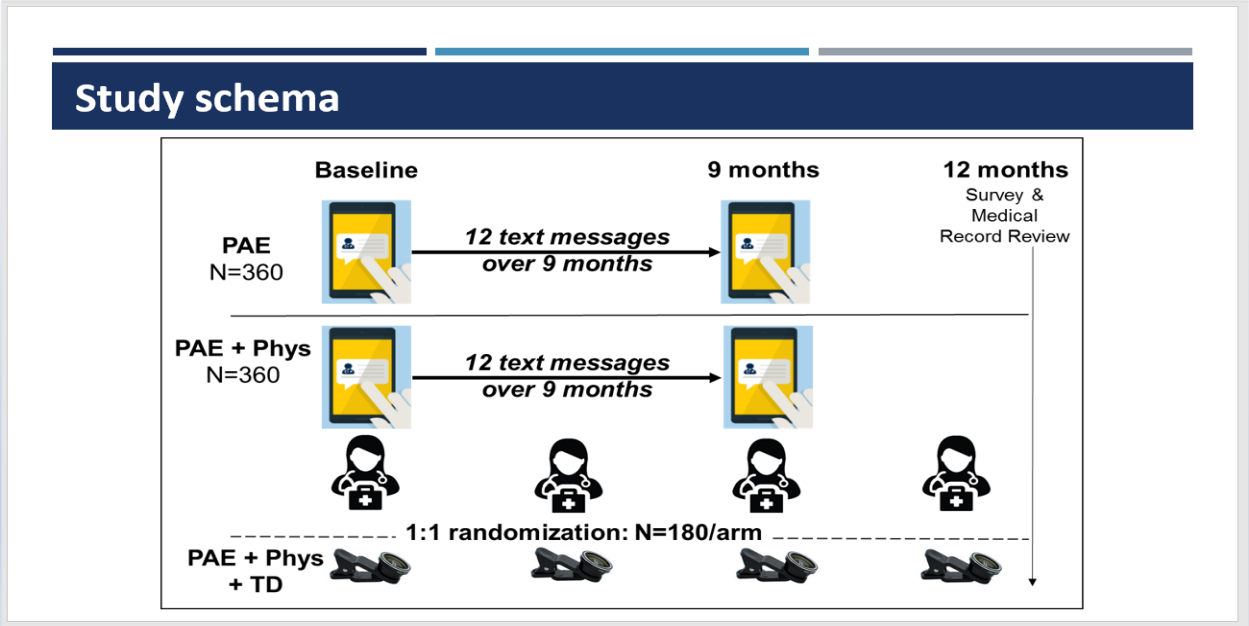
If you agree to take part in this study, you will be randomized to 1 of the 2 intervention plans. Randomization means that the intervention is assigned based on chance. It is a lot like flipping a coin, except that it is done by computer. You will have an equal chance of being assigned to any of the intervention arms. The reason for randomization is to make sure we have an unbiased assignment to each group.

Some will be randomized to Patient Activation and Education (**PAE**) while others will be randomized to PAE plus additional PCP-related education (**PAE+Phys**). The two groups are described below:

INTERVENTION #1: **PATIENT ACTIVATION AND EDUCATION (PAE)**	**You will receive:** • 12 text messages (once every 3 weeks) over 9 months. These messages remind you of the importance of skin self-examinations, PCP skin exams, and to bring the printable checklist to your next PCP appointment; • 2 questionnaires (20 minutes) that ask about your last skin self-examination, any recent PCP skin exam(s), and your general understanding of skin cancer; • printed materials* about your skin cancer risk and instructions on how to do a skin self-examination; and • a printable checklist to take with you to your PCP.
INTERVENTION #2 **PHYSICIAN EDUCATION (PAE + PHYS)**	**In addition to the above, your PCP will receive:** • a letter that describes the study and encourages a full-body skin examination at your next visit with him/her; • information about your increased risk of skin cancer as of BMT survivor; and • images of suspect moles and lesions for educational purposes; and • instructions on how to perform a full-body skin examination; • link to our study website that provides supplemental material for skin exams. • brief (less than 15 minutes) questionnaires at enrollment and 1 year regarding the PCP's self-confidence and general understanding of BMT and its associated risks; and • questions about their type of practice, years of practice and and experience with skin cancer screening.

**Note: Even if your PCP decides not to participate, you may keep the printed materials, but will be withdrawn from the study.*

Diagram of Study



Study Procedures for PAE+Phys +Teledermoscopy (TD) Only:

For the participants randomized to PAE+Phys, there will be an additional randomization. Some participants will be randomized again to the PAE+Phys Teledermoscopy (TD). If you are randomized to this group, your PCP will receive the same educational materials as the PAE+Phys. In addition, they will use teledermoscopy (TD) program, involving a device called Dermlite, to send digital pictures of skin lesions through secure electronic transmission to the study dermatologist (skin doctor). This technology magnifies the image of your skin so worrisome skin lesions can be further examined by a study dermatologist in a remote location. Your PCP will send these images to the study dermatologist to review. Within one week, the study dermatologist will give feedback to your PCP about the image(s) they received. If you do not hear back from your PCP regarding your results, you should contact him/her 14 days after any pictures were taken.

In addition, your PCP will be asked to view a less than 20-minute video on dermatoscopy. This video will provide information and instructions for using dermatoscopes in their practice. . The overall goal of TD technology is to help reduce cost and wait times associated with seeing a dermatologist.

C. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be on this study for about 1 year.

D. WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks of this study are as follows:

Risks associated with Questionnaires:
Some of the questions in the questionnaires may make you feel uncomfortable or anxious. The questionnaires that are being used for this research study have been used in a previous study. To the best of our knowledge they have not caused anyone serious problems. You do not have to answer any question that you don't want to. In addition to the risks described above, there may be unknown risks, or risks that we did not anticipate, associated with being in this study.

Risks associated with Breach of Confidentiality*:*
There is a small risk that people who are not connected with this study will learn your identity or your personal information.

Incidental Findings:
It is possible the research procedures could find a medical problem unrelated to the purpose of this study that you did not know about before. If during the research procedures we learn information that may be important for you to know about, such as the possibility of a previously unknown medical condition, we will tell you. You may authorize the release and communication of the findings to your personal doctor. These findings may require additional testing or treatment. You will be responsible for the cost of any additional tests or related treatment.

E. HOW WILL YOUR INFORMATION BE KEPT CONFIDENTIAL?

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.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, National Institute of Health (NIH)

- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- Regulatory agencies such as the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the National Cancer Institute (NCI) in the U.S., and similar ones if other countries are involved in the study as required by law.

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.

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

The information that have been collected for this study will not be used for future research studies or shared with other researchers beyond the research activities described in this consent form.

F. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS RESEARCH STUDY?

We hope this study will help you personally, but we do not know if it will. Taking part in this study, may or may not help you better understand your skin cancer risk and learn how to perform a skin self-examination. If you end up having a full-body skin exam from your PCP, alerting your PCP to any skin changes, and/or having images send to the study dermatologist may lead to a faster referral to a dermatologist and possibly early detection of any problems. We expect that the information learned from this study will benefit other patients in the future.

G. WHAT OTHER OPTIONS ARE THERE?

Your alternative is to not participate in this study. Choosing not to participate will not affect your ability to receive care at City of Hope.

H. ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

You and your PCP will each receive modest compensation for your time and effort spent on the study. You and your PCP will each receive a $40 gift card at the following 2 time points:

1. At the time of enrollment (baseline)
2. 1 year (end of study)

Additionally, your PCP's office manager/admin will receive a one-time $25 gift card.

If you receive more than $600 per year for taking part in one or more research studies, you may be required to pay taxes on that money. This does not include any payments you receive to pay you back for expenses like parking fees. You may receive an Internal Revenue Service (IRS) Form 1099 if you receive more than $600 in one year for taking part in one or more research studies.

I. WHAT ARE THE COSTS?

Neither you nor your insurance carrier will be charged for participation in this study. It is possible that you may be charged by your phone company for receiving study-related text messages (if your cell phone has limited text-messaging services).

J. WHAT HAPPENS IF YOU GET INJURED AS A RESULT OF THIS STUDY?

If you think you have been hurt by taking part in this study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form. City of Hope will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You

will be responsible for deductible and co-payments, or any costs not paid by your insurer. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

K. WHAT ARE YOUR RIGHTS IF YOU TAKE PART IN THIS STUDY AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

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 City of Hope.

L. WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

The principal investigator, Dr. Saro Armenian, or a member of their research staff has offered to and will answer any and all questions regarding your participation in this research study. If you have any further questions or in the event of a research related injury, you can contact Dr. Saro Armenian at (626) 218-7320.

This study has been reviewed and approved by the Institutional Review Board (IRB). If you have any questions regarding your rights as a research participant, you may contact a representative of that Board, from the Office of Human Research Subjects Protection, at (626) 256-HOPE (4673) ext. 62700.

M. SIGNATURE SECTION

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, 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

FOR USE WITH IRB APPROVED TRANSLATED SHORT/LONG CONSENT FORMS FOR NON ENGLISH SPEAKING PARTICIPANTS ONLY

NOTE:

To determine who should sign below, review the guidance document, *Consenting Non English Speaking Research Participants (Pediatric or Adult) – Who Signs What?*

Interpreter: By signing here, I attest that I have acted as interpreter and facilitated this consent process.

_____ _____ _____

Interpreter's Signature Date Time

_____

Print Interpreter's Name

FOR USE WHEN A WITNESS IS REQUIRED:

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name

IRB #20096: Technology-Enabled Activation of Skin Cancer Screening for Hematopoietic Cell Transplantation Survivors and their Primary Care Providers (TEACH)

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 National Cancer Institute ("NCI"), the National Institute of Health ("NIH") will have access to your PHI.

Your information will also be shared, with the National Institute of Health (NIH), the "Research Sponsor" and its employees, agents, contractors, and any external collaborators who are involved in the administration of the Study.

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 consents only, 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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Interpreter's Signature Date Time

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Print Interpreter's Name

FOR USE WHEN A WITNESS IS REQUIRED:

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name