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City of Hope

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES
IRB #20430: Helping Oncology Patients Explore- Genomics (HOPE- Genomics) Web Tool Randomized Clinical Trial

KEY INFORMATION

You are invited to participate in a research study. The purpose of this research study is to test the effectiveness of a web-based education tool that provides patients with information about their personal genomic test results and education about cancer and genomics in general. The tool is called HOPE-Genomics. If you choose to take part in the study, your participation is expected to last a total of 12 months. You will be randomly placed into one of three study groups and asked to interact with the HOPE-Genomics tool before and/or after receiving your genomic test results from your provider. You will also be asked to complete a total of five surveys over the course of 9 months. Each survey is estimated to take 15-30 minutes of your time to complete. These surveys will ask you about yourself, your experience using the HOPE-Genomics tool, and some general questions about cancer and genetics. While risks are minimal, you may become tired or emotionally upset while completing study-related surveys. The knowledge gained from your participation may not benefit you directly but will be used to help future patients with genomic testing at City of Hope. Your alternative is to not participate in the study, which will not interfere with any future treatment at City of Hope.

I. **PURPOSE OF THIS RESEARCH STUDY**: You have been asked to participate in this research study because:

- You receive your care at City of Hope, you have or had been diagnosed with cancer and you are undergoing genomic testing (a type of test that can identify changes in your DNA), or
- You receive your care at City of Hope, you are being evaluated for an elevated risk of developing cancer and you are undergoing genomic testing (a type of test that can identify changes in your DNA)

The purpose of this study is to test the effectiveness of a web-based cancer education tool called Helping Oncology Patients Explore Genomics (HOPE-Genomics) in improving patient knowledge of personal genomic testing results and cancer and genomics in general.

- 15-30 minutes for a baseline survey
- 15-30 minutes for a survey about cancer and genomics prior to receiving your genomic testing results

- 15 to 20 minutes to view the tool on your own time, before and/or after receiving your genomic test results from your provider
- A total of 45 to 90 minutes to complete three follow-up surveys approximately 10 days, 3 months and 9 months after receiving your genomic test results; each questionnaire will take at least 15 to 30 minutes

We anticipate that about 465 people will participate in the study.

II. **BACKGROUND**: Recently, doctors and other health care providers have started using genomic testing of tumor/leukemia cells and non-cancer cells ('genomic tests"). Often, these genomic tests can help to identify medications that may be particularly effective or identify patients who may be at high-risk for developing cancer. In addition, genomic tests can sometimes tell doctors and patients about the patient's prognosis (outlook) and help to make an exact cancer/leukemia/blood disorder diagnosis in situations where the diagnosis is not clear. However, cancer genomic tests can be confusing, and patients often forget about the results of their genomic tests, even after they have discussed the results with their health care provider. HOPE-Genomics is a web-based education tool that we are developing to teach cancer/leukemia patients, and patients who may be at high-risk for developing cancer, about genomic testing and to provide patients with information about their own genomic test results.

III. **WHAT WILL BE DONE**: If you agree to participate in this study, you will be "randomized" into one of three study groups. Randomization means that you will be put into a group by chance. It is like pulling a number out of a hat. Depending on the group you are randomly placed into, you will be asked to view the HOPE-Genomics tool before and/or after receiving your genomic test results from your provider. This is the only difference between the three study groups.

Regardless of which group you are randomized to, you will participate in the following:

- *Baseline survey (15-30 minutes)*
  i. You will complete an initial survey that asks you a little about yourself, if you have had genomic testing in the past, and about genomics in general.

- *Survey prior to receiving your test results (15-30 minutes)*
  You will complete a survey 2-3 days after completing the baseline survey that will ask you general questions about cancer and genomics. This survey will be completed prior to receiving your genomic test results from your provider. We are asking patients to complete this survey to help us better understand how much patients know about genetics and cancer. This survey will also help us determine whether the educational information in the HOPE-Genomics tool is helpful for patients.
- *HOPE-Genomics viewing session (15 to 20 minutes)*
  i. You will be asked to view the tool on your own time. Depending on the group you are randomized to, you will be asked to view the tool before and/or after receiving your genomic test results from your provider. You will be provided with login information and directions to access the app. To log into the tool, you will be required to input your email, personalized password, and a verification code

texted to your registered mobile device. If you have any difficulty accessing the app, our study team will be available to assist via phone, email, or web-conference meeting.

- *Follow-up surveys (15 to 30 minutes each)*
    i. You will complete three follow-up surveys approximately 10 days, 3 months, and 9 months after receiving your genomic test results. The surveys will ask you general questions about cancer and genomics, as well as your experience interacting with the HOPE-Genomics tool. We will use your responses to improve the tool, so that it is clear, informative, and useful for future patients at City of Hope.

We are also asking for your permission to review your medical record so that we can learn about your health, health care and about the genomic testing that you have had in the past (if any).

Additionally, you have the option to receive updates related to study participation and to receive survey links via text message (standard text messaging rates will apply). Your decision to receive text message notifications is entirely voluntary. If you decide to receive text messages, you may decide at any time that you no longer want to receive them and may cancel by contacting the HOPE-Genomics study team. Your decision to use the service will not affect your ability to take part in this study.

Texting over mobile phones does carry security risks because text messages are not encrypted. This means that information you receive by text message could be intercepted or viewed by an unintended recipient or by your mobile phone provider or carrier. To minimize risks, the messages will not identify you individually and will not include any reference to your course of care at City of Hope. We will not disclose your mobile phone number to anyone outside of this study without your prior permission and consent. If you decide to opt-in for the text message reminders, you may receive:

- One (1) introduction message
- Reminder messages to complete a study procedure (e.g., viewing the platform or completing a survey) (up to 5 messages per study activity)
- Messages with unique survey links (up to 5 messages)

The cost of messages will vary depending on your mobile carrier and on your per message transaction cost. You can consult your mobile carrier regarding your per message transaction cost.

Should you feel upset while completing the study, you may stop participating in the viewing session(s) or surveys at any time. You may also choose not to answer any question for any reason.

All information learned from this study will be kept confidential and secured in the principal investigator's office.

Discontinuation of Participation: There may be circumstances in which your participation in this study may be terminated by the investigator without your consent if it is determined to be in your best interest. These circumstances include if your health status or care plan affect your eligibility to participate.

IV. **POSSIBLE BENEFITS**: You will not benefit directly from participation in this study. Potential benefit to others may result from the knowledge gained from your participation in this research study.

V. **POSSIBLE RISKS AND DISCOMFORTS**: There are no physical risks to participating in this study. You may feel upset when answering study-related questions. If you do feel upset and would like to talk to a psychosocial provider (psychologist or social worker), let us know. We are available to discuss any concerns raised by participation in the survey and can help you to find additional support. The probability of these risks is considered to be low to moderate.

Questionnaires: You may become tired from the amount of time needed to fill out the questionnaire. 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.

VI. **ALTERNATIVES TO PARTICIPATION**: Your alternative is to not 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 the 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), the Agency for Healthcare Research and Quality, the National Institutes of Health, the American Cancer Society, 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.

VIII. **OFFER TO ANSWER QUESTIONS**: The principal investigator, Dr. Stacy Gray or a colleague, 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. Stacy Gray at (626) 256-HOPE (4673) ext. 85495.

IX. **SPONSOR OF THIS RESEARCH**: The National Institutes of Health and National Human Genome Research Institute (NHGRI) are the sponsors of this research study.

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

XI. **PAYMENT TO THE RESEARCH PARTICIPANT FOR PARTICIPATION**:
For your participation, you will receive 3 electronic or physical gift cards at different time points, totaling $25. You will receive a $5 gift card after completing your 10-day follow-up survey, a $10 gift card after completing your 3-month follow-up survey, and another $10 gift card after completing your 9-month follow-up survey. You can opt to have your gift cards emailed to you or mailed to the address of your preference.

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 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.

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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; and 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, as applicable, the Food and Drug Administration (FDA) and the National Cancer Institute (NCI), will have access to your PHI.

Your information will also be shared, with the National Institutes of Health, the "Research Sponsor" and its employees, agents or contractors 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 are 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.