UNIVERSITY OF WASHINGTON
CONSENT FORM
"Cancer Catchment Pilot Study: Clinical Outcomes for Offering Genetic Testing in a Tiered Approach"

Researchers:

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We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

This study is a capacity building partnership between Seattle Cancer Care Alliance (SCCA) Clinical Genetics and Genetic Counseling and Olympic Medical Cancer Center (OMC) Hematology and Medical Oncology service teams in order to improve access and utilization of genetic counseling and testing amongst OMC cancer patients.

- Your consent is being sought for research and participation is voluntary.
- You may refuse to participate and you are free to withdraw from this study at any time.
- If you consent to participate in this study, you will receive coaching from the SCCA medical geneticist and genetic counselor on how you can increase access to genetic counseling and testing for eligible patients at OMC.
- You are free to use your clinical judgement for implementation of the coaching from SCCA in your practice. This study does not dictate how you carry out your clinical care.
- The duration of this study is 6 months.
- This study aims to address current gaps in caring for high-risk patients in a rural and underserved setting. It aims to improve the utilization of genetic counseling and testing among providers at OMC.
- Receiving coaching from the SCCA medical geneticist and genetic counselor will require time from your regular day-to-day schedule. Enrolling in this study will also require you to grant permissions to release your patients' PHI to SCCA. Although data safety monitoring guidelines will be followed throughout the course of this study, transfer of PHI can pose security concerns and breach of confidentiality issues.
- If you enroll in this study, you will participate in bi-monthly conference meetings with the SCCA's research team to receive coaching and guidance related to genetic counseling and testing. You will also facilitate the transfer of your patients' medical records to SCCA.
- Your patients' medical records will be collected by SCCA as part of this research.

PURPOSE OF THE STUDY

This study aims to (1) review and develop OMC's clinical operations workflow to identify cancer patients who meet criteria for genetic counseling and test; (2) measure uptake of genetic testing; and (3) document clinical and patient reported outcomes following genetic test results. Overall, this study will improve utilization of genetic counseling and testing amongst community-based providers caring for cancer patients in a rural and underserved area.

STUDY PROCEDURES

This study is designed in two phases, each phase is done over a 3-month period for a total study duration of 6 months. The SCCA study team will be enrolling eligible OMC providers who will handle all patient interaction and communication.

Phase 1: The first phase does not involve intervention; OMC will be following their existing processes. OMC will gather identified data on the patient's clinic diagnosis, stage, pathology report features, and treatment options for patients with the above diagnoses. OMC providers will have the option to include a standardized Family History Questionnaire (FHQ) filled out by their patients as part of the initial clinical intake and review. OMC will gather de-identified data on the number of patients seen with a diagnosis of breast, ovarian, prostate, colon, and pancreatic cancer. The above data will then be sent to the study's research coordinator at SCCA (through secure email) which will be stored in a secured J-Drive folder within the SCCA network. The research coordinator willrandomly assign all identified patient data to a unique participant ID before distributing to the SCCA cancer geneticist and/or genetic counselor for review. From OMC's collected data, SCCA subject matter experts will measure how many patients met NCCN criteria for testing how many patients were referred to genetic counseling and how many either had a test online or were seen at UWMC and the SCCA for a genetic evaluation.

Phase 2: The second phase involves a tiered intervention in which the SCCA cancer geneticist and genetic counselor will provide OMC providers guidance on offering genetic counseling and testing to their patients. OMC providers are free to decide whether or not to implement the coaching in their clinical care. First, patients and their families fill out the standardized FHQ before/at their initial appointment. OMC and the study's research coordinator will follow the same processes for data gathering, storage, participant ID assignment, and distribution as described in Phase 1. The SCCA cancer geneticist and genetic counselor would then review this information with the OMC providers at a bi-monthly virtual conference. For patients who meet NCCN criteria, the OMC oncology team would include in their initial visit workflow to discuss importance of genetic risk assessment and offer the option of genetic testing. For the patients with a more complicated history, the OMC team would offer a referral to the SCCA for a complete cancer risk assessment evaluation.

At the end of phase 2, the SCCA research team will measure how many patients met NCCN criteria for testing how many patients were referred to genetic counseling and how many either had a test online or were seen at UWMC and the SCCA for a genetic evaluation. This data will

then be compared with phase 1 data to measure the effectiveness of SCCA's coaching for OMC's providers as well as quality improvement of their processes.

INVOLVEMENT IN THIS STUDY

Phase 2 of this study involves a tiered intervention in which the SCCA medical geneticist and genetic counselor will provide you with guidance regarding the utilization of genetic counseling and testing for your patients. As noted, it is your decision to include their recommendation and change processes in your and your team's clinical practice.

RISKS, STRESS, OR DISCOMFORT

This study involves a time commitment and will require you to designate time from your schedule to participate in bi-monthly virtual conferences (~1 hour each). If you decide to implement the coaching from SCCA in your clinical care, time will be required to discuss genetic counseling and testing with your eligible patients as well as ordering genetic testing. For patients who decide to undergo genetic testing, you may allocate extra time at patients' follow-up visits for review of their genetic results.

This study requires you to grant permissions to SCCA to collect your patients' medical records (which will be sent from OMC; SCCA will not have direct access to OMC's medical records). Although strict data safety guidelines will be followed throughout the course of this study and both OMC and SCCA follow HIPAA guidelines, this may pose security concerns and a breach of confidentiality for your patients.

BENEFITS OF THE STUDY

This research will improve patient access to genetic testing and identification of previously undetected genetic predispositions in a patient's family. Offering your patient and their at-risk family members in cancer screening, surveillance, and prevention programs will help to decrease their risk of cancer to as close to zero as possible. Overall, this study will improve utilization of genetic counseling and testing for patients at OMC.

SOURCE OF FUNDING

The study team is receiving funding from the National Cancer Institute (NCI), which will be received and administered by the University of Washington's Office of Sponsored Programs.

CONFIDENTIALITY OF RESEARCH INFORMATION

Patient data will be confidential and linked to identifiers. The SCCA study team will only have access to your patients' medical records that are sent directly from OMC; SCCA will not have direct access to OMC's electronic medical records systems. All patient medical records will be

randomly assigned to a unique participant ID by the study's research coordinator before distributing to the SCCA medical geneticist and genetic counselor in order to maintain strict confidentiality. All reported patient information will be deidentified. The information that we obtain for this study might be used for future studies. We may remove anything that might identify you (or your patient) from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you (or your patient). If we do, a review board will decide whether or not we need to get additional permission from you.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify subjects in the study even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is March 31, 2021. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact Lauren Santos, research coordinator, at 206-606-2557

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact the study's research coordinator listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my patients' medical records as described in the consent form.

To consent to this study, please email the study's research coordinator, Lauren Santos, at lgsantos@seattlecca.org