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Onco-primary care networking to support TEAM-based care – the ONE TEAM Study

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Onco-primary care networking to support TEAM-based care – the ONE TEAM Study

CONCISE SUMMARY

The purpose of this study is to improve chronic disease management and enhance communication among cancer patients, both during and after treatment, by engaging Primary Care Providers (PCPs) as active members of the cancer care team through a multi-level intervention that can be generalized, adapted and scaled in other health care systems with or without a survivorship clinic. This 18-month trial is designed for patients with Stage I-III breast, colorectal, endometrial, head/neck, and non-small cell lung cancer; or stage I-IV prostate cancer who are on active cancer therapy; or chronic lymphocytic leukemia or small lymphocytic lymphoma. A multi-level intervention was developed using evidence-based strategies aimed at activating cancer survivors and PCPs and engaging the PCP as an active member of the cancer care team. Its effectiveness compared with usual care will be determined based on the following: (1) laboratory testing for glycated hemoglobin [A1c] (blood sugar) and lipid profile (amount of fats in the blood); and blood pressure measurements; (2) medication adherence; and (3) patient-provider communication. We will collect information through your electronic health record (EHR) as well as through patient and provider surveys. Prescription information will be collected from electronic prescribing data (SureScripts) and pharmacy benefit managers like Express Scripts. We will also conduct telephone interviews with patients and focus groups with providers after the study completion.

The risk of physical harm is minimal and adverse events are not anticipated. There is the potential of additional medical expenses if health problems are diagnosed based on laboratory results and blood pressure measurements during the study.

You will receive educational materials describing cardiovascular health risks, and risk reducing interventions to maintain health. This study has the potential to improve the management of cardiovascular comorbidities among adults with solid tumor malignancies. Prevention of cardiovascular disease (CVD) by optimizing CVD comorbidity management can potentially extend life and significantly enhance quality of life. The information gathered from this study could be used to develop interventions aimed at optimizing the management of other comorbidities in the future.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you have Stage I-III breast, colorectal, endometrial, head/neck, or non-small cell lung cancer; or stage I-IV prostate cancer and are on active cancer therapy; or chronic lymphocytic leukemia or small lymphocytic lymphoma. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research

study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of ***Dr. Kevin Oeffinger*** and his research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, ***Dr. Kevin Oeffinger*** will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to improve chronic disease management and enhance communication among cancer patients, both during and after treatment, by engaging PCPs as active members of the cancer care team through a multi-level intervention that can be generalized, adapted and scaled in other health care systems with or without a survivorship clinic.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 800 people will take part in this study at the Duke Cancer Center and at sites within the Duke Cancer Network including DLP Maria Parham Hospital (Henderson NC), Scotland Health Care System (Laurinburg NC), UNC Health Southeastern – Gibson Cancer Center (Lumberton NC), Johnston Health - Johnston Cancer Center (Smithfield NC), and Johnston Health - Johnston Hematology and Oncology of Clayton (Clayton NC).

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will be asked to complete a survey. Your blood pressure will be measured and your blood will be collected to assess the amount of sugar (HbA1c) and fats (lipid profile) in your blood. You will be asked to repeat these assessments at 6, 12 and 18 months from the start of the study. In addition, information about your prescriptions and refills will be collected through electronic prescribing data from SureScripts and from your pharmacy benefits manager. This will include medication information starting 6 months prior to enrollment in this study through the end of the 18-month study period.

You will be randomly assigned (like the flip of a coin) to either the Control group or Intervention group.

If you are assigned to the **Control group**, you will receive current guideline-concordant cancer care. We will also provide information for healthy living during and after cancer and for preparing for transition from cancer therapy to follow-up care. You will periodically receive patient education material on

healthy living via the patient portal or by mail, based on your preference. At the completion of therapy, you will be given the NCI Facing Forward: Life After Cancer booklet.

If you are assigned to the **Intervention group**, you will participate in two phases of intervention.

Phase 1

We will test the effectiveness of a self-guided, informational strategy (iGuide), which will include the following:

- Brief video vignettes with a written summary discussing the importance of cardiovascular comorbidities and how to manage them
- One 50-minute live webinar that will discuss the importance of managing CVD comorbidities during and after cancer therapy and will include a moderator, a cancer specialist, a PCP, and a cancer survivor. If you are not able to attend the webinar, a recorded copy will be sent to you on a USB drive and you will be invited to the next live webinar.
- Your PCP will receive a brief letter from our research team notifying them of your participation in the study and a letter from a cancer specialist
- Your PCP will be asked to participate in a monthly telementoring case-based series and will receive quarterly automated reminder messages from one of the cancer specialists reminding them of the importance of comorbidity management

Phase 2

After the 12-month measurements, based on our assessment, you will be assigned to either the iGuide2 or continue on the iGuide intervention. The iGuide2 will include the following:

- 4 monthly 5-minute video vignettes and worksheets in the method that you prefer (MyChart, online streaming, or on a USB drive)
- Specialist to PCP e-consults where a cancer specialist engages your PCP to manage your cardiovascular comorbidities

At the end of the study, we will conduct telephone interviews to get feedback on what went well and what could be improved regarding intervention delivery. You and your PCP will be mailed a newsletter with a summary of the study findings. In addition, patients in the control group will be sent a copy of the printed materials along with a USB drive with the video vignettes and a recorded webinar.

This is an outlined summary of what will be asked of you:

Timeline	Component
Study entry /Baseline	• Survey (25 minutes) • Blood pressure assessment (5 minutes) • Laboratory assessments (10 minutes)
Randomization #1	• Control group • You will receive current guideline-concordant cancer care; information for healthy living during and after cancer and for preparing for transition from cancer therapy to follow-up care; monthly patient education material on

	healthy living; and the NCI Facing Forward: Life After Cancer booklet.
	OR
	• Intervention group
	  • iGuide
	  • brief video vignettes with a written summary;
	  • live webinars

6-months	• Survey (25 minutes) • Blood pressure assessment (5 minutes) • Laboratory assessments (10 minutes)
12-months	• Survey (25 minutes) • Blood pressure assessment (5 minutes) • Laboratory assessments (10 minutes)

Randomization #2	• iGuide
	  • brief video vignettes with a written summary;
	  • live webinars
	OR
	• iGuide2
	  • 4 monthly 5-minute video vignettes and worksheets

18-months	• Survey (25 minutes) • Blood pressure assessment (5 minutes) • Laboratory assessments (10 minutes)
End of study	• Telephone interview (10 minutes)

Participating in this study is voluntary and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

HOW LONG WILL I BE IN THIS STUDY?
If you choose to participate, you will be in this study for approximately 18 months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Clinically relevant results of this research will be communicated with you at the end of the study through a mailed newsletter.

WHAT ARE THE RISKS OF THE STUDY?
As a result of your participation in this study, there are risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely. No other physical risks are associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information

confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the study. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You will receive educational materials describing cardiovascular health risks, and risk reducing interventions to maintain health. This study has the potential to improve the management of cardiovascular comorbidities among adults with solid tumor malignancies. Prevention of cardiovascular disease by optimizing CVD comorbidity management can potentially extend life and significantly enhance quality of life. The information gathered from this study could be used to develop interventions aimed at optimizing the management of other comorbidities in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to the National Institutes of Health (NIH) and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of NIH, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.
If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There will be no costs to you for taking part in this research study. There is the potential of additional medical expenses if health problems are diagnosed based on laboratory and blood pressure measurements during the study. You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study.

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The study sponsor, NIH, has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

WHAT ABOUT COMPENSATION?
You will receive a debit card (Duke ClinCard) which will be loaded with $25 after each assessment is completed for a possible total of $100 for your expenses related to your participation (parking, gas, and time).

Payment for participation in research is considered taxable income and Duke University is required in many cases to report this information to the Internal Revenue Service (IRS).

Duke University requires that you provide your name, mailing address, and social security number for this tax reporting purpose before payment can be issued. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

Research subject payments to a non-employee of Duke University adding up to $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

Research participant compensation made to a Duke University employee at any time during the calendar year will result in a 1099 (Miscellaneous Income) form being issued to the employee and a copy sent to the IRS regardless of the total amount paid.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Kevin Oeffinger at (919) 668-2122 during regular business hours.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study

purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Kevin Oeffinger in writing and let him know that you are withdrawing from the study. His mailing address is Duke University Medical Center, DUMC Box 2714, Durham, NC 27710.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at anytime without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your samples and data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Kevin Oeffinger (Duke University Medical Center) at (919) 668-2122 during regular business hours.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time