Official Title: LCI-GER-NOS-TAB-001: Pilot Study of a Tablet to Administer the Cancer-Specific Geriatric Assessment (CSGA) in Geriatric Patients With Cancer
IRB-Approved Date: 6/12/2018
NCT03419468

CAROLINAS HEALTHCARE SYSTEM
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**A Pilot Study of a Tablet Versus Written Format To Administer The Self Geriatric Assessment Measure (SGAM) In Geriatric Patients With Cancer**
Protocol Number:	**LCI-GER-NOS-TAB-001**
Principal Investigator:	**Daniel Haggstrom, MD**
Telephone:	[redacted] **(24 Hours)** [redacted] **(24 Hours)**
Address:	**Levine Cancer Institute** [redacted]

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date your name at the end of this form. You cannot take part in this research study until you sign and date this form.

INTRODUCTION

Dr. Haggstrom and his associates (the investigators) are asking you to participate in a research study at Levine Cancer Institute (LCI) and Carolinas HealthCare System (CHS). The purpose of this study is to compare the proportions of patients completing health or health related questions using a hand held electronic device (an iPad tablet) to the patients who complete the same survey using a paper format. The survey is called the **Self Geriatric Assessment Measure (SGAM)**. It is standard practice for these questions to be answered either with assistance from medical personnel or without. F**or the purposes of this study, you will be answering the questions in the clinic using either an iPad or a paper survey without assistance from medical personnel or family members.** You are being asked to take part in the study because you are 70 years or older, and have a diagnosis of malignancy under surveillance or active treatment within the past 5 years.

This is a clinical trial, a type of research study. Your study doctor, or research staff will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You have the option not to participate. You may discuss this study with your friends and family. You can also discuss it with your doctor or research staff. If you have any questions, please ask your doctor or research staff.

This study is being carried out under the sponsorship of Levine Cancer Institute (LCI).

WHY IS THIS STUDY BEING DONE?

This study is being done to see if differences exist in survey results among participants who take the survey using either an iPad or paper. The purposes of this study are the following:

- To assess if you can complete all or most of the survey using an iPad without assistance versus you completing the same survey on paper
- To evaluate and compare the total time it takes to complete the survey using an iPad versus using the paper survey
- To understand any technical problems (e.g., screen freezes, battery charge not sufficient and others) encountered by you if you were using an iPad to complete the survey

This is an observational study therefore You will **not** receive any treatments or additional medications as part of this study. Data will be collected by assessing your ability to use the iPad tablet or the paper survey. Based on the survey results we may learn about the various challenges that elderly patients face during their treatment, if and how that affects their ability to receive care and their overall health status.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 89 people will take part in the study. Men and women who are 70 years of age or older who are willing to learn and use an iPad tablet and/or use a paper survey to complete the assessment questions can participate in this study.

HOW THE STUDY WORKS

Before you begin the study

At the beginning of your visit, your doctor or research staff will explain this study to you with the help of the informed consent. They will also answer any questions you may have. If you agree to participate in this study, you will be asked to sign this informed consent.

During the study

Once you are in the study, you will be "randomized" into one of the two study groups based on how the SGAM is viewed and completed. Therefore, one group will use an iPad and the other will take a paper based survey to complete the SGAM.

Randomization means that you are put into a group by chance. This is a 2:1 randomization study, meaning for every two subjects assigned to use the iPad, one will be assigned to fill out the paper survey. A computer program will place you in one of the study groups. Neither you nor your study doctor can choose the group you will be in.

If you are assigned to the iPad survey group:

If you are in the group that requires you to use an iPad to complete the survey, you will be issued an iPad tablet which has the SGAM survey loaded. You will be asked to complete the survey in the clinic. The survey is an assessment that checks on the status of your general health based on measures that allow doctors to personalize your care. It won't ask you any questions about your personal health information. For example, you won't see questions that ask for your name, date of birth, etc.

Here are some other examples of questions that you are likely to see:

- Can you use the telephone without help, with some help or are you completely unable to use it?
- Does your current health limit you in activities like carrying groceries, climbing one flight of stairs or walking one block?
- Is your daily life full of things that are interesting to you?

You will be provided with a brief tutorial on the iPad itself including how it works to answer the questions in the survey. On completion of this tutorial and after entering your study ID number in the indicated space within the survey, no further assistance from the research staff will take place unless you ask for it.

The start time will be the time when your study ID is entered by research staff and the stop time is when you complete the survey and return the iPad to the research staff. You may complete the questions at your own pace.

If you are assigned to the paper survey group:

The paper survey will have the same questions as the iPad survey. You won't be asked any questions about your personal health information.

Instructions will be provided about the marking of your answers. On completion of this tutorial and after entering your study ID number in the indicated space within the survey, no further assistance from the research staff will take place unless you ask for it.
The start time will be the time when your study ID is entered by research staff and the stop time is when you complete the survey and return it to the research staff. You may complete the questions at your own pace.

After you complete the study

Once you complete the survey, you will return either the iPad tablet or the paper survey to a research staff member. Your responses will be saved to a password protected database and the tablet will be cleared of your responses before it is used again. Your information will be viewed by designated research staff by using a secured login and **not** anyone who is not involved with your care. Your responses will also be saved for future use by Dr. Haggstrom and his associates to help make decisions related to your care.

RISKS

This study has no anticipated risks related to the use of the iPad tablet survey or the paper survey. **You are not receiving any treatments or additional medications for being a part of the study.** The main risk to you as a participant in this study is accidental release of the information you provided for the questions asked. But the assessment does not contain any questions that are considered to be are a part of your personal health information or personal information.

Confidentiality Risks

Your privacy is very important to us and we will use many safety measures to protect it. However, despite all the safety measures that we will use, we cannot guarantee that your identity will never become known.

WILL I BENEFIT FROM PARTICIPATING IN THIS STUDY?

There will be **no** direct benefit to you because of your participation in this study. Future research with your information **may** help to improve quality of life, side effects of drugs, improve efficiency and decrease costs that are involved in caring for the older cancer patients.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your alternative is to not participate in this study. If you decide not to be in the study that will **not** in any way harm your relations with your doctors or with Carolinas HealthCare System.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no additional cost to take part in this study. An iPad tablet will be loaned to you for your use in the clinic during this study.

You will not receive payment for taking part in this study. For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage You can print a copy of the "Clinical Trials and Insurance Coverage" information from this web site. Another way to get the information is to call [redacted] and ask them to send you a free copy.

There are no costs to you associated with this study.

None of the doctors asking you to participate in this study has received or will receive money or other benefits for personal use.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

This study is requesting that you answer questions about your health either on an iPad or on paper during a clinic visit. The likelihood of injury because of participation in this study is very small.

If you are harmed as a result of your participation in this study, inform your doctor immediately so you can access medical treatment. You and/or your health plan will be responsible for this treatment in the usual manner. The study does **not** pay for medical treatment.

WHAT IF I WANT TO QUIT THE STUDY LATER ON?

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. Your participation for this study will be for one day. If you choose to withdraw from the study, please notify the study doctor in writing at the address on the first page of this form.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Carolinas HealthCare System (CHS)
- Government agencies, like the Food and Drug Administration (FDA) that are involved in keeping research safe for people

The records of this study will be kept private. Any data shared with others will be de-identified after entry into our data system so that your identity will be protected. In any sort of report, we might publish, we will not include any information that will make it possible to identify you as a study participant. Your record for this study may, however, be reviewed and/or photocopied by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. All your study data will be kept in a secure location.

A description of this clinical trial will be available on 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.

AUTHORIZATION:

If you wish to take part in this study, you will be asked to sign this consent form. It allows the study sponsor (LCI) and the study investigator (Dr. Haggstrom) to collect and process any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history, demographic information) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- The clinical study investigator, Dr. Haggstrom, and his research staff
- Regulatory or other governmental authorities of the United States,
- The study sponsor (Levine Cancer Institute)
- Carolinas HealthCare System employees
- Other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- Check your suitability to take part in the study,
- Compare results with those of other subjects in the study,
- Support the development of the other study protocols.

You have been told that your personal information may be processed within the U.S. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record. You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctor, in writing at the address on page 1 of this consent form.
Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

FINANCIAL DISCLOSURE

None of the doctors asking you to participate in this study have received or will receive financial benefit in any form from the study.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;

- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff at Carolinas HealthCare System, listed on the first page of this form, with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB) and was determined to be exempt from IRB oversight. For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the study team, you may contact:

- By mail:
  Study Subject Adviser
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the study subject adviser: Pro00023842.

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent