Are you participating in any other research studies? _____ Yes _____No

## PURPOSE OF RESEARCH

You are invited to participate in a research study of Serious Illness Conversation Guide (SICG). We hope to learn if the Serious Illness Conversation guide will improve discussions pertaining to end of life care, thereby providing you with a care plan that is consistent with your values and wishes. You were selected as a possible participant in this study because you meet the requirement to participate in this research study.

If you decide to terminate your participation in this study, you should notify Tyler P. Johnson, MD at 650-725-5071.

This research study is looking for patients with advanced cancers of the Gastro-intestinal tract who are being treated at the Stanford Cancer Center. We expect to enroll 68 research study participants.

## VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

## DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 12 months.

## PROCEDURES

If you choose to participate, you will be assigned 1:1 by chance (a process called randomization) to one of two groups.
If you are assigned to Group 1 (control arm), you will continue with your current care. You will be asked to complete a survey at baseline and every 3 months.

If you are assigned to the second group (Intervention arm), you will be scheduled for a separate clinic visit where you will meet with a research team to undergo a series of conversations as outlined in the Serious Illness conversation guide. This conversation will be repeated every 3 months.
In addition, you will be asked to complete a survey at baseline and every 3 months thereafter.

## PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

## WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Tyler P. Johnson at 650-725-5071

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

## POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. You may experience mild emotional distress or feel uncomfortable when answering questions or speaking of your personal experience.
These deserve careful thought. You should talk with the Protocol Director if you have any questions.

## POTENTIAL BENEFITS

Information learned from the study may help other people in the future.
We cannot and do not guarantee or promise that you will receive any benefits from this study.

## ALTERNATIVES

Your other choices may include:

- Getting treatment or care for your cancer without being in this study.

## PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.
You will be told of any important new information that is learned during the course of this research study, which might affect your willingness to continue participation in this study.

## CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

**Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.**

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.

# Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

## What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of the study is to determine whether the Serious Illness Conversation Guide will facilitate conversations regarding end of life goals and to ensure patient care is aligned with their wishes.

If you choose to participate, the study staff will obtain personal information about you for research purposes. This may include medical and research records that may identify you and that may describe your health. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations without written permission from you.

## Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.
Signing the form is not a condition for receiving any medical care outside the study.

## If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to Tyler P. Johnson at 875 Blake Wilbur Drive Stanford, CA 94305.

## What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, your name, address, phone number, medical history, date of birth, and information from your study visits. This health data may come from your family doctor or other health care workers.

## Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Tyler P. Johnson, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

## Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**

Your authorization for the use and/or disclosure of your health information will end on December 31, 2030 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

## FINANCIAL CONSIDERATIONS

Payment/Reimbursement
You will not be paid to participate in this research study.

Costs
There may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

## COMPENSATION for Research-Related Injury

This research study has no known risk for research related injury.

## CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Tyler P. Johnson. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

Signing your name means, you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant