The Ohio State University Consent to Participate in Research

Study Title: Efficacy of an Educational Food Safety Intervention for Cancer Patients Receiving Treatment

Principal Investigators: Sanja Ilic

Sponsor: College of Education and Human Ecology

Study Summary: The purpose of this study is to deliver and evaluate food safety training that will help cancer patients, who are receiving treatment, make more informed decisions of how they prepare foods safely and make better choices of low-risk foods. We seek to address awareness of foodborne infection, appropriate food preparation practices, and understanding of what foods present increased risk for cancer patients. As detailed below, your participation is voluntary and is not linked, in any way, to the receipt of your treatment at this facility. Further, you may withdraw your consent at any time. There are no expected risks or harms from participating in this study. As a part of this training, you will fill out a survey, then complete up to 30 minutes of digital training, and then complete a similar survey. We will follow up with you in five weeks, at which point you will complete a final survey, which will let us know how well our training addressed long-term knowledge. As a thank you, for taking your time to complete these tasks, we are giving you two $10 gift cards, as well as both a food thermometer and a refrigerator thermometer. Thank you for your participation. For more details, as well as research staff contact information, please see below.

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you

decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

This study is being done to determine the efficacy of a food safety educational program on food safety behaviors among cancer patients. It is an initial step to help us understand the effects of food safety education on cancer treatment outcomes and patient wellbeing.

2. How many people will take part in this study?

If you decide to be in this study, you will be one of 75 people in this research study.

3. What will happen if I take part in this study?

If you agree to be in the study, you will be asked to:

- Complete a survey: The survey is made up of questionnaires that will assess information about your food safety knowledge and behaviors, your health status, and any cancer treatments you are currently receiving.
- Complete an educational training: The training will address aspects of food safety that are specifically important to cancer patients receiving treatment.
- Complete a second survey: The survey is made up of questionnaires that will assess information about your food safety knowledge and behaviors, your health status, and any cancer treatments you are currently receiving.
- Complete a third survey: Five weeks from the completion of this training, you will be contacted by research staff to complete a final survey. The survey is made up of questionnaires that will assess information about your food safety knowledge and behaviors, your health status, and any cancer treatments you are currently receiving.

4. How long will I be in the study?

Completing two of the questionnaires and training will occur in one study visit and will take about 50 minutes to complete. The third questionnaire will be sent to you five weeks after you complete the initial training and surveys and will take about 10 minutes to complete.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are

otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

This study does not pose any substantial risk to you, since you will only be completing surveys and an educational training. We do however realize that the release of confidential data may occur despite our measures to maintain confidentiality. As such, specific identification numbers will be used to code your information during collection, handling and management, to prevent identification of your data. All data collected will be password protected.

7. What benefits can I expect from being in the study?

The direct benefits to you will be the information you receive from completing the educational training, which is hypothesized to positively impact your well-being. This study will also provide researchers and policy makers with information essential for the development of effective interventions, needed to prevent foodborne diseases among cancer patients.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by Office for Human Research Protections or other federal, state, or international regulatory agencies; and The Ohio State University Institutional Review Board or Office of Responsible Research Practices.

10. What are the costs of taking part in this study?

There are not costs for participating in this study.

11. Will I be paid for taking part in this study?

You will receive one gift card worth $10 for completing the first portion of this study, and an additional $10 gift card for completing the follow-up survey in 5 weeks. By law, payments to subjects are considered taxable income. You will also receive educational

literature concerning food safety for patients undergoing cancer treatment, as well as both a food thermometer and a safety thermometer for use in your refrigerator.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center. The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Sanja Ilic at 614-292-4076 (ilic.2@osu.edu).

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 research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Sanja Ilic at 614-292-4076 (ilic.2@osu.edu).

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM**
	Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time