Participant's Name: _____

Participant's MRN: _____

Participant's Study ID: _____

MCC #:19733

CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION
STUDY 2

Study Title:	**Motivating a spectrum of cancer patients to quit smoking: intervention development and feasibility**
Sponsor:	**National Institutes of Health**
Principal Investigator:	**Ursula Martinez Ph.D.**
Telephone: **(24 hour number)**	**813-745-1754** **800-456-3434**
Address:	**H. Lee Moffitt Cancer Center and Research Institute, Inc.** **Tobacco Research and Intervention Program (TRIP)** **4115 E. Fowler Avenue** **Tampa Fl 33617**

We (the study researchers and staff at Moffitt Cancer Center) study diseases and other health problems people may have. Our goal is to try to find better ways to help treat these health problems. To do this, we sometimes ask people to take part in research studies.

If you have any questions about or do not understand something in this form, you should ask the study researchers and study staff. Discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. Being in this study does not replace your regular medical care.

WHAT IS THIS STUDY ABOUT?

This study will collect feedback from cancer participants about some new information materials designed specifically for patients who smoke.

You are being asked to be in the study because you are (1) 18 years of age or older; (2) You recently received a diagnosis of breast, colorectal, gynecological, skin melanoma, or bladder cancer at Moffitt Cancer Center; (3) You are a current smoker or you have smoked in the past;

(4) able to read and write English; (5) not currently enrolled in a smoking cessation program; (6) able to give informed consent;

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 50 participants will take part in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

Following the informed consent, you will be asked to complete a baseline questionnaire and will be given the intervention materials. You will be contacted a week and a month later for a follow-up assessment.

Throughout the study you may receive study-related emails for appointment reminders, surveys, etc. By verbally agreeing to participate in this study, you are agreeing to opt-out of encrypted emails to receive study related materials. This may increase risk for a breach of confidentiality if another individual has access to your email account. Please ask the study staff if you have any questions about how to best protect study-related information in your email account.

WHAT ARE MY ALTERNATIVES TO BEING IN THIS STUDY?

You do not have to be in this study. Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you, and you won't lose any benefits.

WHO IS PAYING FOR THIS STUDY?

An organization called the National Institutes of Health (NIH), the sponsor of the study, is paying for this study.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

It will not cost you anything to be part of this study.

WILL I GET PAID?

You will be compensated a total of $50 for your participation. You will be compensated $15 for completing the pre and post assessment and $20 for the one month follow up.

WILL BEING IN THIS STUDY HELP ME?

We cannot promise any direct benefit for taking part in this study. This research may lead to the development of interventions to help cancer patients to increase their motivation to quit smoking. Participation may motivate some participants to quit smoking, which has multiple health benefits.

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ARE THERE RISKS TO ME IF I AM IN THIS STUDY?

There are minimal risks associated with this study. We will take specific steps to reduce these risks. You may feel upset thinking about or talking about personal information while completing questionnaires. These risks are similar to those you experience when discussing personal information with others. If you feel upset from these experiences, you can tell the study researcher, and he/she will tell you about resources available to help.

DO I HAVE TO REMAIN ON THIS STUDY ONCE I JOIN?

Your participation in this study is voluntary. You are free to refuse to participate in the study or withdraw your consent at any time during the study. Your decision will not result in any penalty or loss of benefits to which you are entitled. The principal investigator reserves the right to remove you without your consent at such time that they feel it is in the best interest for you.

If you want to stop taking part in this study, contact the principal investigator or the study staff at the telephone number listed on the first page of this form.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your verbal authorization before we use or disclose your information for this study.

By providing verbal consent to participate, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

Information that you share during this program will be kept confidential, and may only be shared with the study staff. However, there are situations in which confidentiality may be broken for your safety and the safety of others. These situations include but are not limited to: disclosing that you may have thoughts or plans to harm yourself or others, reports of possible abuse to a child, elderly person, or vulnerable adult. Under these circumstances, the study staff may contact the appropriate authorities and disclose information that has been shared during the interaction in order to protect the safety of you and those individuals potentially at risk of harm.

MOFFITT CANCER CENTER INJURY STATEMENT

If you believe you have been injured as a result of your participation in this study or if you have questions about your rights as a person who is taking part in a research study, you may call the Moffitt Cancer Center Risk Manager at 813-745-4219. Moffitt Cancer Center and its investigators have made no provision for monetary compensation in the event of physical illness

or injury resulting from this study. Likewise, Moffitt Cancer Center and its investigators have made no provision for payment of lost wages, disability, or discomfort in the event of physical illness or injury resulting from this study. Florida law (Statute 768.28) limits the liability of Moffitt Cancer Center. This statute provides that damages are available only to the extent that negligent conduct of a Moffitt Cancer Center employee caused your injuries, and are limited by law. A copy of this statute is available upon request at 813-745-1869.

WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?

Your records are confidential and they will be kept in a secure environment and protected to the full extent of the law

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, USF and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: National Institutes of Health.
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA) and Florida Department of Health (FDH). The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, USF IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study investigator and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy

regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?

By providing verbal consent, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study investigator listed on the first page of this form.

Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You will receive a copy of this form.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. 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.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Participant Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00029255.

WHERE CAN I GET MORE INFORMATION?

You may call the National Cancer Institute's (NCI) Information Service at:
1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

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.

Participant's Name: _____

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NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.

DO YOU WANT TO BE IN THIS STUDY?

You should read this form before agreeing to participate in this research. If you decide not to take part in this study you will not lose any rights you normally have, you will still have the same health care benefits, and you can continue getting care from your doctor.

It is up to me to decide whether I want to take part in this study. Before agreeing to participate, a representative of the Moffitt Cancer Center has answered my questions to my satisfaction.