Smoking Cessation for Cervical Cancer Survivors (Project SUCCESS)

NCT02157610

ICF Version 2 Dated 9/05/2019

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

Study Title:	**"Smoking Cessation for Cervical Cancer Survivors in a Safety Net Healthcare System (Project SUCCESS)"**
Protocol Number:	**MCC 20134**
Sponsor:	**Moffitt Cancer Center**
Principal Investigator: (Study Investigator)	**Jennifer Vidrine, PhD**
Telephone: (24 hour number)	**813-745-1751 800-456-3434**
Address:	**Moffitt Cancer Center Prevention Research, Fowler Campus 4117 E Fowler Ave. Tampa, FL 33617**

You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate.

The purpose of the study is to compare a program called Motivation and Problem Solving (MAPS) to the standard approach to helping patients with a history of cervical cancer or cervical dysplasia to quit smoking.

The study design will randomly place you in to 1 of 2 possible study groups. Your group will be chosen by chance, like the flip of a coin.

Group 1 will receive:
- Free self-help materials
- A referral to the Tobacco Free Florida (or your state's tobacco helpline)
- 12-week supply of nicotine replacement therapy (the patch and lozenges)

Group 2 will receive:
- Free self-help materials
- A referral to Tobacco Free Florida (or your state's tobacco helpline)
- 12-week supply of nicotine replacement therapy (the patch and lozenges)
- 6 telephone counseling sessions over the next year

The Florida Tobacco Helpline, Tobacco Free Florida (1-877-U-CAN-NOW (1-877-822-6669)) is a service that provides free quit smoking services to eligible callers.
You will also be asked to complete questionnaires over the phone, in person, or via a web-based link. You will be asked to complete a questionnaire 5 times. These questionnaires should take about 45 minutes each time to complete. You may also be asked to provide saliva samples.

You are being asked to take part because you are a current cigarette smoker with a history of cervical cancer or cervical dysplasia.

About 450 women will participate in this study overall. Of them, up to 30 women will participate in the in-depth interviews. Up to 20 women will participate in the pilot portion of the study.

Your participation is voluntary, and you may stop the study at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Since this is not a treatment study, your alternative is to not participate.

We do not know if you will receive any benefit from your participation. If you agree to take part in this study, there may or may not be direct medical benefit to you. Taking part in this study may help you control or quit smoking. We hope that the information learned from this study will benefit other patients with this condition in the future.

The most common and most serious risks that may be related to taking part in this research include:

- Side effects from the nicotine patch or lozenges, such as increased heart and blood pressure
- Skin redness
- Symptoms of nicotine overdose like nausea, dizziness, weakness
- Vivid dreams or difficulty sleeping
- Allergic reactions such as difficulty breathing or rash
- Mouth, teeth, and jaw problems
- Indigestion
- Sore throat

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

WHAT IS INVOLVED IN THE STUDY?

No matter which group you are in, you will receive a 12-week supply of nicotine replacement therapy (the patch and lozenges). The strength of the nicotine patches and lozenges you receive will depend on how much you smoke each day. You should use the nicotine patch as directed by the package instructions.

Unused and used patches have enough nicotine to poison children and pets. Be sure to fold the sticky ends together when you are done using the patch. In case of accidental overdose, call your regular doctor or a poison control center right away.

Even if you do not wish to use the nicotine patch, you will be allowed to take part in the study.

Study Questionnaires:
You will be asked to complete questionnaires over the phone, in person, or via a web-based link. You will be asked to complete these questionnaires 5 times. These will occur at the beginning of study and at months 3, 6, 12 and 18. You will be asked about your feelings, moods, cervical cancer or dysplasia diagnosis, and smoking status. These questionnaires should take about 45 minutes each time to complete.

Saliva Testing:
At months 3, 6, 12 and 18, you may also be asked to provide a saliva sample to test for cotinine. Cotinine is a chemical released in your body when it breaks down nicotine. This test is to confirm your smoking status. You will receive a kit in the mail with supplies for testing. The study staff will call you to make sure you received the kit and to discuss the instructions with you. If you have any questions about how to use the kit, you may contact the study staff during the study.

To collect the saliva, you will put a small piece of cotton in your mouth for a few minutes. You will be asked to mail the saliva sample back to the study staff using a prepaid return envelope. During the study, you may be contacted by mail, telephone, and/or email to be reminded to send back the kit.

Telephone Counseling (for Group 2 Only):
If you are in Group 2, you will have 6 telephone counseling sessions. These sessions may last up to 30 minutes each. These calls will occur over a 12-month period at times that are convenient for you. During the calls, you will be asked about how motivated you are to quit smoking, what barriers to quitting you may have, and factors that may be related to your smoking such as stress and family issues.

The telephone counseling sessions will be digitally recorded. Only the study investigators and study staff will be allowed to view or listen to the recordings. Your identity will be kept strictly confidential. Your study identification number will be stated by the counselor at the beginning of the taped session. The recordings are stored digitally, encrypted, and password protected. The telephone counseling recordings will be destroyed 10 years after results from the study are published.

Other Information:
You will also be asked to provide the names and contact information of family and/or friends. Study staff will contact these people if they have trouble reaching you. All study data, including informed consent recordings and telephone counseling session recordings, will be destroyed 10 years after results of the study have been published. All data will be stored in a secured location on one of the departmental servers, which are backed up daily. Only certain members of the study staff or others designated by the study chair will have access to the study data.

WHAT IS THE STATUS OF THE DRUGS INVOLVED IN THIS STUDY?

This is an investigational study. The nicotine patch used in this study is FDA approved and commercially available.

HOW LONG WILL I BE IN THE STUDY?
Your participation in the study will end when you complete the final questionnaire at Month 18.

If you wish to leave the study early, you should tell the study staff that you want to stop being in this research study. You will not receive follow-up questionnaire phone calls after telling the study staff you no longer want to be in the study.

WHAT ARE THE RISKS OF THE STUDY?
While on this study, you are at risk for side effects. You should discuss these with your regular doctor. The known side effects are listed in this form, but they will vary from person to person.

Possible Nicotine Patch Side Effects

- Increased blood pressure
- Skin redness
- Swelling
- Rash
- Irregular heartbeat or palpitations
- Symptoms of nicotine overdose including nausea, dizziness, weakness, and rapid heartbeat
- Vivid dreams or sleep disturbance

To lower the risk of skin reactions, you should put the patch on a different skin area each day. To lower the risk of difficulty sleeping and abnormal dreams, you can remove the patch when you are sleeping and put on a new patch in the morning. To avoid possible burns, you should also remove the patch before undergoing any MRI procedures.

Possible Nicotine Lozenges Side Effects

- Increased heart rate and blood pressure
- Mouth, teeth, and jaw problems
- Indigestion or sore throat
- Irregular heartbeat or palpitations
- Symptoms of nicotine overdose including nausea, dizziness, weakness, and rapid heartbeat
- Allergic reaction such as difficulty breathing or rash

Please contact the Study Investigator, Dr. Jennifer Irvin Vidrine, if you have questions about any of the listed side effects of using the nicotine patches, lozenges, or collecting saliva samples. You should also discuss possible medication side effects with your regular doctor. Many side effects go away shortly after the tobacco cessation medications are stopped. Sometimes side effects can be serious or long lasting and permanent. The tobacco cessation medications may involve risks that are not yet known.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaires, you are encouraged to contact your regular doctor or the study investigator.

IS THERE ANY RISK TO YOUR UNBORN CHILDREN IF YOU TAKE PART IN THIS STUDY?

FOR WOMEN:

If you are pregnant, you cannot participate in this study, because there may be risks to you and your unborn baby that are currently unforeseeable; risks that we do not know about yet. Breastfeeding (nursing) mothers will not be included in this study, since it is not known whether the drugs in this study will be passed on to the baby in mother's milk. If you are currently breastfeeding and wish to continue breastfeeding, your study investigator may recommend another smoking cessation option.

Tell the principal investigator right away if:

- You are pregnant.
- You become pregnant.
- You are planning to become pregnant.
- You are breastfeeding.

There may be risks to your unborn children that we don't know about ahead of time; they are unforeseeable.

If you take part in this study, you must use an effective birth control method as discussed with your study investigator.

Examples of birth control methods include:

- Oral birth control pills
- Birth control patch
- Implanted (injectable contraceptive hormones or mechanical products such as intrauterine device)
- Barrier methods (such as: diaphragm, condoms, or spermicides)
- Tubal ligation
- Abstinence (no sexual intercourse)

You should discuss the method of birth control which is best for you to use both during the study and for a period of time after the study.

You should tell your study investigator immediately if you become pregnant. If you do become pregnant during the study, you should discontinue use of the nicotine patch and/or lozenge and consult with your physician before resuming use of these products.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

There is no cost to participate.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you need emergency care:

- Call 911 or go to your nearest emergency room right away. Moffitt Cancer Center does not have an emergency room or the facilities to provide emergency care.

If you do NOT need emergency care:

- Call or go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

By agreeing to participate in this study, you have not given up any legal rights to seek compensation for injuries from the sponsor**.**

WILL I GET PAID?
You will receive retail gift cards for your time and cooperation in the study. You may receive up to $420 total in gift cards over the course of the 18-month study:

- $30 gift card for the completion of assessments at Baseline, months 3, 6, 12 and 18
- $30 gift card to compensate for the use of your cell phone minutes at Baseline, months 3, 6, 12, and 18.
- $30 gift card for returning a cotinine saliva sample, if you're asked to provide one

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

ARE THERE REASONS THE STUDY INVESTIGATOR OR SPONSOR MIGHT TAKE ME OUT OF THE STUDY LATER?
Even if you want to stay in the study, there may be reasons the study investigator or study staff will need to take you out of it. Your study investigator has the right to take you out of the study at any time with or without your agreement. Your participation may be ended without your consent for different reasons.
Some reasons include the following:

- If the study investigator believes for any reason that it is in your best interest.
- If other causes prevent you from continuing in this study.
- If the Sponsor decides to end the study.

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 of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By agreeing to participate in this study, 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.

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

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. The following people 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, 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.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- 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)).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra 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. 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 agreeing to participate, 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. Also, the purpose is to ensure that the information relating to the 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. 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 study 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 participants.

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 study 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 have questions, concerns or complaints about the study, please contact the study investigator at the telephone number listed on the first page of this consent document.

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
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser:Pro00036882

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.

STATEMENT OF CONSENT AND AUTHORIZATION

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. I authorize the use and disclosure of my personal health information for the use of this study. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records.

_____

Printed Name of Participant

_____ _____ _____

Signature of Participant Date Time

STATEMENT OF PERSON OBTAINING INFORMED CONSENT / RESEARCH AUTHORIZATION

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____

Printed Name of Person Explaining Consent

_____ _____ _____

Signature of Person Explaining Consent Date Time