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

AIM 3

Study Title:	**Utilizing Augmented Reality as an Adjunct for Smoking Cessation, Development and Initial Validation**
Protocol Number:	**MCC 20007**
Sponsor:	**NIH**
Principal Investigators:	**Christine Vinci, PhD** **Thomas Brandon, PhD**
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Address:	**Moffitt Cancer Center** **4115 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 create a new addition to stop-smoking treatments that may improve treatment. We are developing an app using augmented reality. Augmented reality is when a computer-made image is inserted into a real-world environment.

Your participation will require:

- Completing an online survey of general demographic information about yourself, your tobacco use history, behaviors, and beliefs.
- Downloading an augmented reality app on your smartphone to be used for 7 days.
- With this app, you will be asked to view several augmented reality images at least five times per day for seven days and provide brief ratings on your urge to smoke, and how many cigarettes you have smoked.
- Completing an online follow up survey within one week after finishing your seven-day app use. The follow-up survey will ask you about your experiences using the app and your smoking attitudes.
- Finally, you will be asked to complete a brief follow-up interview one week after completing the app use by phone in which you will be asked additional questions about your experiences using the app.

Your follow-up interview will be audio recorded.

You will also receive free self-help materials for quitting smoking to use if you desire.

You are being asked to take part because you currently smoke, you have a smartphone, and you are motivated to quit smoking. About 20 participants will take part in this phase of the study.

Your participation is voluntary, and you may stop your participation 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.

We do not know if you will receive any benefit from your participation. This study is for research purposes only; the only alternative is to not participate.

Are there any costs to me for taking part in this study?

No, there will not be any costs for taking part in this study.

You will be compensated with up to $80 in e-gift cards.

You will get $10 for each of two online surveys and one follow-up phone interview you complete. If you complete these within 24 hours, you will be compensated a bonus of $5 for each. You will receive your compensation for each of these after completing the survey or interview. You will also get $5 for each of the 7 days that we ask you to use the smartphone study app. This payment will be sent to you when you complete the second survey.

The most common risk that may be related to taking part in this research is that your information may accidentally not be kept confidential. You will be audio recorded during the interview. It is possible that your voice may be recognizable and your identity becomes known. However, we have many steps in place to protect your confidential information that make a breach unlikely. You will always be given the option to refuse to answer any questions that may be distressing. There may be unforeseen risks that are not known to the study staff.

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.

ARE THERE REASONS THE PRINCIPAL INVESTIGATORS OR SPONSOR MIGHT TAKE ME OUT OF THE STUDY LATER?

Even if you want to stay in the study, there may be reasons the Principal Investigators or study staff will need to take you out of it. The Principal Investigators have 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, including the following:

- If the Principal Investigators believe, for any reason, that it is in your best interest.

- If other causes prevent you from continuing in this study.
- If you do not complete the study requirements within the time limits set for each portion of the 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 because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By giving your verbal agreement to participate in this study, you are permitting researchers at Moffitt Cancer Center to use personal responses to questions for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your responses to questions 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 responses to questions 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, 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, 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 sponsor of the study, including the following sponsors: NIH
- 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, 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 Principal Investigators 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.

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 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 investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT INFORMATION WILL BE USED OR DISCLOSED?

By giving your verbal agreement, you authorize the use and disclosure of your entire study record. 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 information will never expire unless and until you expressly revoke it in writing to the Principal Investigators 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 do not need to agree to be in the study, but if you do not, you cannot participate in this study.

You will receive a copy of this form.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you 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.

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: Pro00032586.

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.

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