Multi-site Research Consent Form

Title of Research Study: QuitGuide for American Indians: Aims 2 & 3

This is a multi-site research study, meaning that the study is taking place at several locations. This consent includes two parts to explain the study. Part 1 describes the key information you need to know before deciding to participate in this study. Part 2 includes additional information about how the study will be carried out at this location.

Investigator Team Contact Information: ***Dana Mowls Carroll, PhD, MPH***
This study is being led by Dana Carroll at the University of Minnesota. To learn who is leading the study at this location their contact information, see Part 2 of this consent form.

For questions about research appointments, the research study, research results, or other concerns, call the study team listed in Part 2 of this consent form.

Supported By: This research is supported by a grant (R21CA261078) provided to Dr. Dana Carroll from the National Cancer Institute.

University of Minnesota Financial Interest Disclosure: The study team has no financial interest in the outcome of this study.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are an adult who smokes commercial cigarettes, identifies as American Indian, has a smartphone, and is willing to participate in a study that involves using a smartphone app for quitting smoking.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to assess the ease of use and satisfaction with a version of the National Cancer Institute's QuitGuide smartphone app that has been developed for American Indian adults. This study will also explore the impact of the app on smoking behavior and use of other resources for quitting smoking.

How long will the research last?

You will be in the study for approximately 5-6 weeks.

What will I need to do to participate?

Your participation will include completing online surveys, downloading an app onto your smartphone and engaging with the app, and setting a date to quit smoking. You will also be asked to provide a saliva sample and mail it to the University of Minnesota. We will mail you all the saliva collection items and pre-paid packaging to mail it back to us. Finally, some participants may complete a recorded interview with the research coordinator on their experiences in the study.

More detailed information about the study procedures can be found under *"What happens if I say yes, I want to be in this research?"*

Is there any way that being in this study could be bad for me?

The potential risks of this study are minimal and include the risks associated with the loss of confidentiality, boredom of participating, and nicotine withdrawal. More detailed information about the risks of this study can be found under. More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include quitting smoking or become more prepared to quit smoking.

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the key information listed above.

What happens if I say "*Yes, I want to be in this research*"?

Screening Procedures

If you are interested in enrolling in this study, we will determine if you are eligible by asking you several questions over the phone that include questions on demographics, commercial tobacco use, interest in quitting, and smartphone ownership.

Study Procedures

If you are eligible and interested, you will be enrolled in the study. You then will be asked to complete an online survey. You will then be randomized to a version of the QuitGuide smartphone app that has been developed for American Indian persons OR a version of the QuitGuide smartphone app that has not been specifically developed for American Indian persons. Upon opening the app for the first time, you will set a quit date for one week later. We will ask you to use the app as much as you can for 5 weeks. We are interested in how people may use this app in the real-world. We encourage you to use it daily but ultimately how much you use it is up to you. If your quit date arrives and you are not ready to quit or if you quit but do not remain cigarette free, you will have the option to reset your quit date in the app and continue in the study. At week 4, you will be mailed a saliva sample collection kit with instructions to provide the sample when you complete the 5-week follow-up survey, and materials (e.g., pre-paid envelope) will be provided so that you can return the sample to the University of Minnesota. At 5 weeks, you will complete a follow-up survey and provide your saliva sample. Finally, you may be asked to participate in a phone call or virtual/online exit interview with the research coordinator, who will ask questions to learn a bit more about your experiences in the study.

After the study period, you will be able to continue to use the version of the app that you used while in the study unless you purposely delete it from your smartphone. If you are interested in using the other version of the app (the one you were not assigned to during the study), we will help you access that version and download it to your phone.

Study Interventions/Randomization:

You will be randomized to: 1) a version of the QuitGuide smartphone app that has been developed for American Indian persons or 2) a version of the QuitGuide smartphone app that has not been developed specifically for American Indian persons.

Specific details about where the procedures will take place locally, are listed in Part 2 of this consent form.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. If you decide to leave the research study, please let the research team know. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student (if applicable), or your present or future employment. If you stop being in the research, already collected information about you will not be removed from the study database.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

This research may have the following negative effects and you should be aware of these before deciding to be part of the study:

Symptoms of Nicotine Withdrawal

If you quit smoking or reduce cigarettes as part of the study, symptoms of nicotine withdrawal can occur which can be brief but uncomfortable. Symptoms of nicotine withdrawal may include headache, dizziness, restlessness, nausea, anger, irritability, frustration, anxiousness or nervousness, depressed mood or sadness, desire or craving to smoke, difficulty concentrating, increased appetite/hunger, weight gain, insomnia, impatience, constipation, nightmares, sore throat, and coughing. These symptoms can present among people who quit outside of research studies and are not just exclusive to this study.

Survey Questions

You will be asked several questions about your smoking history, demographics, use of traditional tobacco, identification with American Indian culture, and several factors that may influence your smoking behavior. Answering these kinds of questions may make some people feel uncomfortable.

Privacy & confidentiality risks

There is some risk of a data breach involving the information that you provide to us. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will it cost me anything to participate in this research study?

Taking part in this research study may lead to added costs to you. These added costs may result from using the internet/Wifi on your smartphone to engage with the smartphone app.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including study records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP)).

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of the study will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

For additional information about what information might be shared with authorities, see "What may be shared with authorities?"

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

What will be done with my data and specimens when this study is over?

Your data and your saliva sample will not be used for any future research after this study is complete.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include if you do not comply with the study activities/requirements.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company.

Will I be compensated for my participation?

You can earn up to $125 for your time and effort. If you complete the survey and visit today, you will be compensated $25. If you complete the exit survey within 48 hours of email receipt to complete it, you will receive $25. If you complete the exit survey but not within 48 hours, you will receive $10. If you return the saliva sample, you will receive $25. If you complete all these activities, you will receive a $50 bonus.

Study activity	Compensation
Baseline virtual visit & survey	$25
Exit survey	$25 if completed within 48 hours or $10 if completed not within 48 hours
Returned saliva sample	$25
Bonus for completing all activities listed above	$50
Total possible compensation*	**$125**
*Additional possible compensation will be made available to some participants for completion of a follow-up interview (invite only): $25	

For how you will be compensated at this location, ***"How will I be compensated at this location?" in Part 2 of this consent.***

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PART 2: LOCAL STUDY INFORMATION FOR UNIVERSITY OF MINNESOTA AND AMERICAN INDIAN CANCER FOUNDATION

Who can I contact if I have questions?

Local Investigator Name: Dana Mowls Carroll Investigator Departmental Affiliation: Division of Environmental Health Sciences Phone Number: 612-624-0132 Email Address: dcarroll@umn.edu Local Investigator Name: Wyatt Pickner Investigator Departmental Affiliation: American Indian Cancer Foundation Phone Number: 612-484-9667 Email Address: wpickner@americanindiancancer.org	Local Study Staff (if applicable): Amika Kamath Study coordinator Phone Number: (612)-308-2144 Email Address: Carrollresearch@umn.edu

How many people will be studied?

We expect about 116 people here will be in this research study.

Where will study activities take place locally?

All study procedures will occur remotely.

What may be shared with authorities?

If we learn about current or ongoing child or elder abuse or neglect, we may be required by law or policy to report this information to authorities. In addition, if we learn that you intend to harm yourself or others, we may be required to report this information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting or a recording of your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting or a recording of your consent meeting without your permission ahead of time.

How will I be compensated locally?

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address and date of birth. They will use this information as part of the payment process. Greenphire will only need your social security number if the payment exceeds $599. Greenphire will not receive any information about your health status or the study in which you are participating.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

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Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent