Official Title: The Impact of Cannabidiol (CBD) Health Claims at Point-of-Sale on Consumer Perceptions and Behavior: Mini Mart Randomized Control Trial (RCT)

NCT06800066

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Wake Forest®
School of Medicine

Department of Social Sciences and Health Policy

**Understanding consumer purchase behavior within a mock-store environment**
Informed Consent Form to Participate in Research
*Kimberly Wagoner, DrPH, MPH,* Principal Investigator

## SUMMARY

You are invited to participate in a research study. The purpose of this research is to better understand how people make decisions when shopping in a retail store. You are invited to be in this study because you indicated that you are between the ages of 18 and 79. Your participation in this research involves 1 in-person visit to our study office which will last about 1 hour.

Participation in this study will involve shopping in the UNC Mini Mart in Chapel Hill, NC. You will also be asked to complete a survey after the shopping task is complete. All research studies involve some risks. A risk to this study that you should be aware of is completing surveys with sensitive items and an accidental breach of confidentiality**.** There are no direct benefits from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Kimberly Wagoner, DrPH, MPH. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

## How Many People Will Take Part in the Study?

If you decide to take part in the study, you will be one of about 490 people in this study.

## WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

You will complete an in-person appointment at the study offices of the UNC Mini Mart, in Chapel Hill, NC. You will be given directions on how to complete a shopping task in the UNC Mini Mart. You will then take a survey, at the study office.

## What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You may feel discomfort while answering the survey. You have the option to skip questions you do not feel comfortable answering. You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

## Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

## What Are the Costs?

It will not cost you anything to be in this study. You may have to pay for transportation to the study office. You will not be reimbursed for this cost. You will receive a parking pass to park at the study site, if needed. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

## Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law.

## WILL YOU BE PAID FOR PARTICIPATING?

You will be paid an incentive valued at $75 after you complete the scheduled shopping task and survey.

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**: name, age, and contact information**. We will make every effort to keep your Protected Health Information private. We will assign you a unique numerical identifier to be used on all study documents. We will maintain an electronic version of your name, identifier, and contact information on a secure, password-protected server that can only be accessed by study personnel. The only individuals who will have access to the information are the Principal Investigator, and research staff. We will delete your personal information from the computer six months after the study ends.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Kimberly Wagoner that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Kimberly Wagoner
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This could be because you failed to follow instructions or because the entire study has been stopped. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

**Participant's Agreement:**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

***Participants will be shown a link that says "I consent."***