Official Title: Habitual Diet and Avocado Trial
NCT03528031
IRB-Approved Date: 2/11/2021

HABITUAL DIET AND AVOCADO TRIAL (HAT)

Supplement Informed Consent Form for Biobank sample storage

Penny Kris-Etherton, PhD, RD, Principal Investigator
The Pennsylvania State University, University Park

You are invited to be in a research study called the Habitual Diet and Avocado Trial (HAT). The principal investigator listed above is in charge of the study at Penn State. Other people, such as study coordinators or research nurses, may help or act for him/her.

This supplement informed consent document is to ask for your permission to use and store your samples for future research in addition to the research that is described in the main Study Informed Consent Form.

Participating in this part of the study is voluntary. Please read this information carefully before deciding to take part. You may take as much time as you need to ask questions with the study team, with family and friends, or with your personal physician or other healthcare professionals. The study team will answer any questions you have before you make a decision. If you do not want your samples to be stored and used for future research, you can still take part in the Habitual Diet and Avocado Trial (HAT).

PURPOSE OF THE COLLECTION AND STORAGE OF SAMPLES:

If you consent specifically, we would like to store samples for use in future research. Future research may provide additional information that will be helpful in understanding diabetes and other diseases related or potentially related to diet. If you do not want your samples to be stored and used for future research, you can still take part in the Habitual Diet and Avocado Trial (HAT).

- **Blood Samples:** If you agree, a blood sample will be collected and may be used in future research by investigators associated with the Habitual Diet and Avocado Trial.
- **DNA sample:** If you agree, some of the blood sample that will be obtained at the baseline visit will be used to study your genes (also called DNA). DNA, or deoxyribonucleic acid, stores and transmits inherited traits, such as eye color or blood type. As part of the research projects arising from HAT, your DNA will be studied in an effort to find out if there are genes that contribute to diabetes and other diseases related or potentially related to diet. Because we do not know how the results of this DNA study relate to your individual health, the results of the research will not be given to you or your doctor. These results will also not be placed in your medical records.

WHAT HAPPENS DURING THE STUDY?

At visits 2, 5 and 8, blood will be drawn from a vein in your arm. About one and a half teaspoons (6.5 ml) will be stored for future research. Your stored blood sample will be used only for research and will not be sold. Some of the blood samples that will be obtained at the baseline visit will be used to study your DNA. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

WHAT ARE THE RISKS?

You may experience discomfort, swelling, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy, lightheaded or feel faint. Infection may occur in rare occasions.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

The research that may be performed with your stored blood sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your samples will not be given to you or your doctor. The results will not be put in your medical record.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Participating in this part of the study is voluntary. You can choose not to participate. If you do not want your sample(s) to be used in this additional research, you can still take part in the main study.

If you decide to participate in this optional sample storage part of the study, you can decide to stop participating at any time in the future. If you choose to withdraw consent to store your samples, your decision will be respected and any samples remaining in storage will be destroyed. It will not be possible to retrieve or destroy any samples once they have been shared with other researchers. If you decide withdraw your samples from future use, you can call the Principal Investigator, Dr. Penny Kris-Etherton, at [redacted].

WILL MY RESEARCH RECORDS BE CONFIDENTIAL?

In the future, researchers may like to know more about your health. While future researchers may be given reports about your health, he/she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to be contacted in the future by the Principal Investigator or other researchers.

HOW WILL MY HEALTH INFORMATION AND BIOLOGICAL SAMPLES BE PROCESSED, TRANSFERRED AND STORED?

Your samples will be coded. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the information that links the code with your identifiable information. The coded samples will be stored at Dr. Kris-Etherton's locked laboratory for future testing and analysis by our colleagues and collaborators. Only researchers that have their research proposal approved by the Institutional Review Board (IRB) may use your coded sample.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Penny Kris-Etherton, at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

PARTICIPANT'S STATEMENT OF SUPPLEMENT CONSENT FOR BIOBANK SAMPLE STORAGE

I have had the opportunity and sufficient time to review the study information, ask my investigator questions about this study, and my questions have been answered. I understand the conditions and procedures, and I have been informed of the possible risks and benefits from taking part in this study.

Participant Name (Printed):_____

Participant Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent: _____ Date:_____ Time:_____ am pm

Please review the question below and place your initials in the space corresponding to your answer.

AGREEMENT FOR COLLECTION AND STORAGE OF BLOOD FOR FUTURE RESEARCH STUDIES

I agree to allow my blood to be stored for use in future research.

_____ YES _____ NO

AGREEMENT TO PARTICIPATE IN GENETIC STUDIES

I agree to allow my genetic sample (DNA) to be used to study diabetes and other diseases related or potentially related to diet.

_____ YES _____ NO