INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**U.S. Department of Agriculture / "Monell USDA Taste Test Study"**
Protocol Number:	**HS65 – MUTT Study**
Principal Investigator:	**David Baer, PhD**
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KEY INFORMATION

You are invited to take part in a research study. This research study is being done to help us understand factors that affect food preference. The U.S. Department of Agriculture (USDA) and U.S. National Institutes of Health (NIH) are co-sponsoring this research study.

The total duration of this study will be 7 months. For this study, subjects will eat a diet of only foods we provide for approximately 3 months. The foods will be typical American foods, and we will provide you with the right amount of food to neither gain nor lose weight. Taste tests will be conducted and a blood sample will be collected at the beginning of the study, every month, and at one time point after the USDA-provided study diet phase is complete.

The main reasons a volunteer might want to join this study would be to enjoy the chef-prepared food provided. The main reason a volunteer might choose not to participate would be because it will require multiple visits to the USDA Nutrition Center (to eat breakfast, to collect supplies, and to drop off the samples), the discomfort of blood collection, the inconvenience of completing the taste tests and questionnaires, and the requirement to eat only the foods we provide and all the foods we provide for 3 months.

Please read this form carefully. Take your time to ask the study investigator or study staff as many questions about the study as you would like. The study investigator or study staff can explain words or information that you do not understand.

Reading this form and talking to the study investigator or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE
You are being asked to participate in this research study because you are a healthy adult.

This study is being done to help us understand factors that affect food preference.

About 90 subjects will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?
Your participation in this study will last up to 7 months and will include approximately 70 study visits to the study center. Most of these visits will be to eat breakfast.

Screening:
Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent document. You will not receive monetary compensation for the screening process. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- You will complete a study application and health history form.
- You will complete a questionnaire about the foods you ate or drank during the last 30 days.
- You will provide a fasted blood and urine sample.
- You will have your height, weight, and waist circumference measured.
- You will participate in a series of taste tests. For the taste tests, you will taste multiple samples and describe them.
- You will participate in a smell test. For the smell test, you will smell 3 samples, and describe the smell.
- Review the study schedule and a list of study foods to confirm that you can eat all of the foods on the menu and participate in all the study procedures.

Once we have received your application, health history form, food questionnaire, blood & urine analyses, taste and smell test results, and height and weight measurements, we will evaluate whether you are eligible to continue in the study. The list below is a list of exclusion criteria; if any of the following apply to you, you cannot participate in the study:

Exclusion Criteria (who cannot participate in the study)

- Younger than 25 years old and older than 80 years old at the beginning of the intervention
- Known (self-reported) allergy or adverse reaction to study foods or ingredients

- A dietary pattern inconsistent with the dietary intervention (for example, vegan, vegetarian, extremes of protein, fat, carbohydrate intake)
- Have body weight less than 110 lbs.
- Body mass index less than 18 or greater than 40 kg/m^2
- Have lost or gained more than 10% of body weight within the last 12 months or who plan to initiate a weight loss program during the next 12 months
- Women who have given birth during the previous 12 months, are pregnant, are lactating, or plan to become pregnant during the study
- Known taste or smell disorders, including weak or absent sense of, abnormal taste in the mouth (for example, bitter or metallic "phantom" tastes), or other taste abnormality
- Use of medications within one month prior to the study that moderately to severely affect taste
- Use of appetite suppressants or other anti-obesity medication during the past 6 months
- History of bariatric or certain other surgeries related to weight control
- Have tested positive for COVID-19 in the past 4 weeks
- History or presence of diabetes, kidney disease, liver disease, certain cancers, gout, hyperthyroidism, untreated or unstable hypothyroidism, gastrointestinal disease, pancreatic disease, other metabolic diseases, malabsorption syndromes, phenylketonuria, or endocrine disorders that may interfere with the study outcomes
- Individuals with any gastrointestinal issues, including inflammatory bowel disease, suspected or known strictures, fistulas or physiological/mechanical GI obstruction, nutrient malabsorption disease, or Crohn's Disease
- Smokers, vapers, or other tobacco/marijuana users within 6 months prior to the study
- History of eating disorders
- Self-report of alcohol or substance abuse within the past 12 months and/or current acute treatment or rehabilitation program for these problems (long-term participation in Alcoholics Anonymous is not an exclusion)
- Other medical, psychiatric, or behavioral factors that in the judgment of the Principal Investigator may interfere with study participation or the ability to follow the intervention plan
- Unable or unwilling to give informed consent or communicate with study staff

If you qualify to take part in this study and go on to the study diet phase, then the following will happen:

<u>Washout Period</u>:
Most dietary supplements will not be allowed during the study. You will be asked to abstain from vitamin, mineral, and herbal supplements beginning 2 weeks prior to the study diet phase, and you will need to continue to abstain for the duration of the study. You will need to have all supplements approved by study staff.

Study Diet Phase:
During the study, you will be consuming a diet fully provided by the USDA for 3 months. During those 3 months, you will eat only foods provided by the USDA Nutrition Center and you must eat all the foods provided to you. The amount of food you will be given will be tailored to your needs such that you are not too hungry nor too full, and your weight will remain stable. The foods will be items typical of an American diet, including meats, vegetables, grains, fruits, sweets, and snacks. You will be able to drink coffee and tea during the study, but the amount will be controlled, and you may not be able to add sugar or sweetener to your coffee. You will be provided with breakfast, lunch, dinner, and a snack daily. You will be expected to eat all the foods provided and only the foods provided by the USDA Nutrition Center during the 3 months of the study diet phase.

During the 3 months, you will consume breakfast Monday through Friday at the USDA Nutrition Center in Beltsville, MD. The dining facility is open from 6:30 AM to 8:30 AM for breakfast. Lunch and dinner will be provided for carry-out and will be available when you arrive at the center for breakfast. The weekend meals will be packaged in a large cooler packed with ice, which you will take with you after you consume your breakfast on Friday.

You will be randomly assigned by chance (like rolling dice) to receive 1 of 3 typical American diets. You will have an equal chance of being in any of the three groups; each study group will include 30 individuals.

Your diet may contain low calorie sweeteners, such as Equal™ (aspartame) and Splenda™ (sucralose). We will use sweeteners approved for use in foods and beverages by the U.S. Food and Drug Administration (FDA) below acceptable daily intake levels. The sweeteners we use will be common sweeteners available in the marketplace. More information about the sweeteners used in this study and their safety can be found at this FDA website:
https://www.fda.gov/food/food-additives-petitions/high-intensity-sweeteners

You will have the following study visits and undergo the following procedures. The following table outlines the timeline of study procedures, which are also described below.

	Week of the Study													
	1-2 weeks before the study	1	2	3	4	5	6	7	8	9	10	11	12	Follow up: 4-12 weeks after the study
Breakfast at USDA		x	x	x	x	x	x	x	x	x	x	x	x	
Daily Questionnaire		x	x	x	x	x	x	x	x	x	x	x	x	
Weight	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Taste Tests	x				x				x				x	x
Blood Draw	x				x				x				x	x
Breakfast Test	x												x	
Saliva Sample	x													
Food record	x													x
Food Cravings Questionnaire	x	x	x	x	x				x				x	x
Diet Questionnaires	x				x				x				x	x

- *Breakfast at USDA*: You will visit the USDA Nutrition Research Center 5 times per week to eat breakfast, pick up lunch and dinner meals, and return your previous food cooler. The dining facility is open from 6:30 AM to 8:30 AM for breakfast. You will meet with a study staff member for a few minutes at breakfast to discuss any concerns or problems you may be having on the study.
- *Daily Questionnaire*: At breakfast, you will complete a one-page questionnaire to record how you are feeling, consumption of medication, the study diet phase, and coffee or tea (2 cups are allowed daily).
- *Weight:* You will weigh yourself every day before breakfast at the USDA Nutrition Research Center and at every visit during the follow-up period after the study diet phase.
- *Taste Tests:* You will participate in a total of 23 taste tests during the study – 8 times before the study diet phase, 12 times total over the 3-month study diet phase, and 3 times after the study diet phase. For these taste tests, you will be provided with 10 food samples made with a different mix of ingredients. You will taste each sample and evaluate the taste. You will complete the taste tests at home or at the USDA Nutrition Center, online with a laptop computer. If you do not have access to a computer, we will provide access. If done at home, the taste tests will be monitored by a member of the study staff over Zoom. The taste test will take 30 minutes to complete.
- *Blood Draws:* You will have your blood drawn 5 more times throughout the study. You will not eat or drink anything (except water) for 12 hours prior to your blood sample

collection time. You will report to the USDA Nutrition Research Center for the blood collection. These blood collections will occur in the morning, before 10:00 AM.

- *Breakfast Test:* You will participate in 3 breakfast tests: 1 time before the study diet phase, 1 time at the end of the study diet phase, and 1 time during the follow-up after the study diet phase. You will be provided with 3 versions of the same breakfast made with a different mix of ingredients. You will taste each version and evaluate the taste. You will then be free to eat as much of the foods provided as you like. The breakfast test will take 30 minutes to complete.
- *Saliva Sample:* You will be asked to provide one saliva sample at the beginning of the study.
- *Food Record:* You will record food intake using an online system called ASA24. You will be given a username and password to log on to an online database to record all of the food you eat throughout the day. The program contains commonly consumed foods and helps determine accurate portions of food consumed. You will keep a record for 3 days (2 non-consecutive weekdays and one weekend day) before the study and after the study diet phase. This record will take up to 30 minutes to complete.
- *Food Cravings Questionnaire:* During the study diet phase, you will fill out a questionnaire 7 times (once a week during the first month of the study, and once a month for the rest of the study) to tell us about your food cravings. This questionnaire is expected to take 5 minutes to complete.
- *Diet Questionnaires*: You will complete 8 questionnaires before the study diet phase, 1 questionnaire each month during the study diet phase, 1 questionnaire at the end of the study diet phase, and 1 questionnaire at the follow-up phase. Each questionnaire will take about 5-20 minutes to complete. Before the study, the questionnaires will be spaced out so you only complete up to 2 questionnaires a day.

<u>After Study Diet Phase</u>:
After the end of the study diet phase, there will be a break between 4 to 12 weeks. After the break, you will complete a follow-up assessment that will include 3 taste tests and a set of questionnaires.

After you have completed the follow-up assessment, the study will be over, and you will consume your self-selected diet, with no further sample collections.

EXPECTATIONS
If you participate in this study, you will be expected to:

- Read, sign, and date this informed consent form.
- Wear a mask at certain times while you are in the USDA Nutrition Center.
- Complete a study application, health history questionnaire, and a diet questionnaire.
- Have your height and weight measured when you deliver your health history questionnaire.
- Provide a blood sample and a urine sample, after eating no food nor drink for 12 hours (except water) during your study screening visit.

- Participate in taste tests and smell tests.
- Consume only and all the foods provided by the USDA Nutrition Center for 3 months during the study diet phase.
- Visit the USDA Nutrition Research Center 5 times per week (6:30 to 8:30 AM Monday – Friday) to eat breakfast, collect food for lunch and dinner, and return your empty food coolers.
- Weigh yourself and record your weight each time you visit the USDA Nutrition Research Center for breakfast and the follow-up visits.
- Complete a questionnaire daily to report how you are feeling, any medications you have taken, and consumption of approved beverages.
- Participate in taste tests 23 times during the study. The taste tests may be conducted online and supervised over Zoom, or the taste tests may be conducted at the USDA Nutrition Research Center. Therefore, you may need to come to the USDA Nutrition Center at your scheduled day and time to complete the tests.
- Fast overnight for 12 hours (no food consumption, but you can drink as much water as you like) before morning blood draws 5 times during the study.
- Complete a 30-minute food record three times before the start of the study diet phase and three times after the study diet phase. This questionnaire is completed online.
- Provide one saliva sample.
- Complete questionnaires multiple times during the study.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

For the Study Diet:

It is common to feel a bit bloated or full when you change your diet pattern. This risk affects about 1/20 subjects and usually resolves within a week.

RISKS OF STUDY PROCEDURES

- Blood samples: Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
- Questionnaires: The questionnaires used in this study may make you uncomfortable. You do not need to answer any questions that you are not comfortable with.
- USDA Prescribed Diet: You may want to eat foods of your choosing, but you will need to eat only our study foods during the study diet phase.

UNFORESEEN RISKS

Additionally, there may be other risks that are unknown.

BIRTH CONTROL RESTRICTIONS

There are no birth control restrictions, and this study poses no risk to pregnancy, pregnant women, fetuses, or lactating women. However, subjects in the study will be maintained at a constant body weight, and pregnancy requires weight gain. Therefore, if you become pregnant during the study, you will be dismissed from the study.

ALTERNATIVES TO PARTICIPATION
You do not have to be in this study. You may talk to the study investigator, family, or friends about your options before you decide whether or not you will take part in this study. This research study is for research purposes only. The only alternative is to not participate in this study.

If you are an employee, your participation or your family member's participation will not place you in good favor with the study investigators, your supervisor, or the study sponsor (for example, increase in salary, promotion, extra vacation, or the like). Not participating will not adversely affect your employment, in particular, the position that you currently hold.

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

BENEFITS
This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION
Compensation will be prorated according to the extent of completion of procedures as follows:

- Completion of Month 1 procedures - $150
- Completion of Months 1 & 2 procedures - $825
- Completion of Months 1 - 3 procedures - $1,500
- Completion of Months 1 - 4 procedures- $2,175
- Completion of Months 1 - 7 procedures - $2,500

You will not be paid to meet with the study investigator to sign the consent form or for the screening visit(s).

Payment will be made only by direct deposit. At the end of Month 3, subjects will be paid for the first 3 months; at the end of Month 7, subjects will be paid for the rest of the study procedures.

For each month, completion of all procedures means arriving on time for breakfast, completion of all questionnaires, weighing and recording body weight at every visit to the USDA Nutrition Center, meeting with a study staff member every week to discuss study issues, and participation in all scheduled blood collection.

If you do not complete the study, for any reason, you will be paid for the portion of the study you complete, as described above.

If there is evidence that you have not complied with the study plan, it is possible that we will remove you from the study. If this happens, you will only be compensated for the visits and procedures you completed in compliance with the study plan.

Compensation for research subjects is considered taxable income. Amounts of $600.00 or more will be reported to the Internal Revenue Service (IRS).

There will be no additional compensation for travel to and from the USDA Nutrition Center.

If you have any questions regarding your compensation for participation, please contact the study staff.

CONFIDENTIALITY

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

Medical and other personal information given in participation of this research is confidential. A law passed by the U.S. Congress, known as the Privacy Act, places strict limits on how federal agencies may use such information, and requires that subjects be informed as to why the information is requested and how it will be used. All information will be kept in strictest confidence. You will be assigned a code number for the study. This number will be assigned at the initial visit and will be used to identify samples and data. Names or other identifiers will only be used for procedures where person-to-person communication is required. You will not be personally identified in any of the reports of research. Deidentified information may be shared with Monell Chemical Senses Center, a collaborator on the study.

Your study records including confidential information about you collected during the study will be kept at a secure location. Data and samples from this study will be disposed of after all publications concerning the study are completed. As required by the U.S. Department of Agriculture, consent forms and medical screening data will be kept for 25 years, and then destroyed. All other data, records, and samples will be kept until manuscripts have been published, and then they will be destroyed. Samples collected at screening will be destroyed immediately after analysis.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner. You may revoke your permission at any time by writing to the study investigator at the address listed on the first page of the form.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

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.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. This information may include your name, address, phone number, date of birth, medical history, and information from your study visits, including test results. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- A limited number of representatives from the study sponsoring company (namely its monitors and auditors)
- The institutional review board – Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study subjects)
- Government regulatory authorities including the U.S. Food and Drug Administration (FDA) and other foreign regulatory agencies

Your health data will be used to conduct and oversee the research, including comparing the study to other similar studies.

Your study records including confidential information about you collected during the study will be kept at a secure location. Your right to access your health data will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

By signing and dating this informed consent and authorization form, you authorize the collection, access, use, and disclosure of your information as described above.

COMPENSATION FOR INJURY

We will make every effort to prevent injuries or illness from occurring while you are in the study. In the case of an injury, illness, or other harm occurring to you during, or resulting from, the study, you should seek medical treatment. You should also contact the study investigator as soon as possible. You or your insurance company will be charged for any continuing medical care and/or hospitalization that are not a part of the study.

If you suffer an injury related to the study procedures, the reasonable costs of necessary medical treatment of the injury will generally not be reimbursed by USDA. If you have an injury or illnesses occurring during, or resulting from, the study, you, your medical insurance, a third-

party payer, or a government program you've enrolled in will be expected to provide coverage for your medical care.

The Federal government does not have any program to provide compensation to you if you experience injury or other bad effects that are not the fault of the investigators. If you are injured while participating in this research project as a result of the negligence of a United States Government employee who is involved in this research project, you may be able to be compensated for your injury in accordance with the requirements of the Federal Tort Claims Act. Compensation from individuals or organizations other than the United States might also be available to you. If you are a federal employee acting within the scope of your employment, you may be entitled to benefits in accordance with the Federal Employees Compensation Act. You still have the right to seek compensation for injury related to malpractice, negligence, fault, guilt, or blame of those involved in the research.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor, or involved institutions from their legal and professional responsibilities.

No funds have been set aside by the USDA or its affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from, the study, and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this, you do not give up your rights to seek compensation in the courts.

COSTS
There will be no charge to you for your participation in this study. The study diet, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

FUTURE RESEARCH STUDIES
Identifiers will be removed from your identifiable private information or identifiable biospecimens collected during this study. Deidentified data **could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent.

COMMERCIAL PROFIT
Your biospecimens collected during this study will not be used for commercial profit.

CLINICALLY RELEVANT RESULTS
Research results that are clinically relevant, including individual research results, will not be disclosed to you. If you contact us after the study is complete and the results have been published, we will provide you with the publication of the results for the study group as a whole.

GENOME SEQUENCING

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading," every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. This research **will include** whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject 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 Subject Adviser: Pro00028988.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please

note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the Investigator may ask you to have some end-of-study tests for your safety.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date