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Consent Form

Study Title: Astringency and Oral

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RUTGERS UNIVERSITY
School of Environmental

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Astringency Perception and Oral Health
Principal Investigator: Beverly J Tepper, PhD, Professor

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. The **purpose of the research** is to study the effect of daily rinsing with a cranberry extract on taste perception, salivary proteins and the composition of the oral microbiome. You will be asked attend a single screening session. If eligible, you will be asked to participate in a 2-week study when you will rinse with a cranberry extract oral rinse twice a day. This oral rinse will be provided to you along with the proper instructions on using it. You will come to the lab for three test sessions: at the beginning, after 2 days, and at the end (14th day) of the study. During the sessions, you will be asked to evaluate beverage samples as well as provide saliva samples by spitting into a plastic tube. Each test session will take about 30 minutes to complete. You will also rinse your mouth with the oral rinse for 30 seconds two times per day at home for 11 days. **There are no harms or burdens** of taking part in the study nor direct benefits of taking part in it. Although, this research will benefit society by providing a better understanding of the relationship between taste and nutrition. Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Beverly J Tepper is the Principal Investigator (PI) of this research study. The PI has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Beverly J Tepper may be reached at the following address: Department of Food Science, Rutgers University, 65 Dudley Road, New Brunswick, NJ 08901.
Tel: 848-932-5417. Email: btepper@sebs.rutgers.edu

The PI or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
Cranberry juice and other cranberry products have strong flavors that are desirable to some consumers and disliked by others. Since cranberries have positive effects on human health including the oral cavity, it is important to know why there are large differences between people in how they perceive these foods.

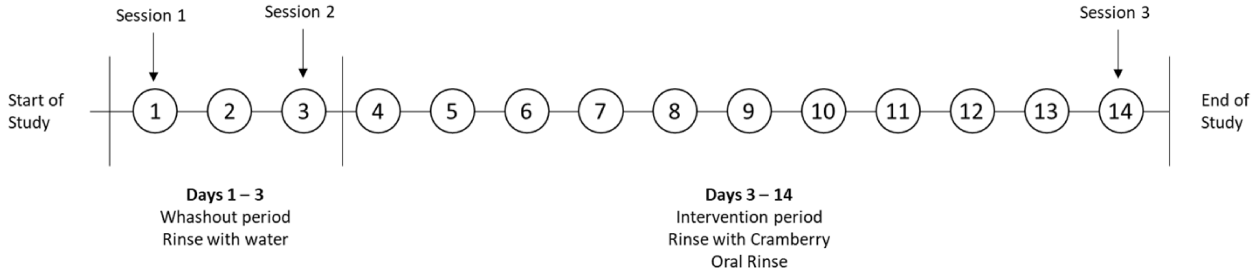
Proteins in saliva play an essential role both in affecting taste perception and in maintaining a healthy oral environment. The purpose of this study is to better understand how genetic factors, salivary proteins and microorganisms that inhabit the oral cavity (oral microbiome) influence oral health.

Who may take part in this study and who may not?
Healthy, non-smoking males and females aged 18-50 are eligible for the study. You may not take part in this study if you are pregnant or nursing, if you have a taste or smell disorder or if you are taking medication affecting taste or smell. You will also be excluded if you have any of the following conditions: diabetes (Type I or Type II), heart problems, blood problems (i.e., clotting, kidney disorder, hypertension, stroke), asthma, hay fever/ allergies, cancer, or sinusitis.

Why have I been asked to take part in this study?
You are invited to participate in this research because you meet the general criteria for the study.

How long will the study take and how many subjects will take part?
You will participate in a 15-minute in-lab screening session to determine your eligibility for the study. If you qualify for the study and agree to participate, the duration of your participation is two weeks. Approximately 350, but no more than 500, individuals will participate in the screening. A target number of 60 subjects will complete the study. The study is expected to be completed in approximately 1 year.

What will I be asked to do if I take part in this study?
If you are interested in taking part in this study, you will sign the consent form which starts the screening process.
In the screening session, you will be asked to taste filter paper disks that may or may not have a taste to you. The ability to taste one of these substances (called PROP) is a genetic trait. You also will be asked to complete brief questionnaires about your health and eating habits.
If you qualify for the study and wish to participate you will take part in the following activities according to the timeline shown below.
1st session: you will be asked to provide a small saliva sample by spitting into a tube. Your saliva will be analyzed for taste related genes. You will complete questionnaires on your food preferences and eating habits. Between session 2 and 3, you will be asked to rinse with water twice a day (in the morning and in the evening).
Sessions 2 and 3: you will be asked to evaluate juice samples as well as provide saliva samples by spitting into a plastic tube. The saliva samples will be analyzed for salivary proteins, and microbial profiles (oral microbiome). Between session 2 and 3, you will be asked to rinse, at home, with a cranberry extract oral rinse twice a day (in the morning and in the evening) for 11 days.



What are the risks of harm or discomforts I might experience if I take part in this study?
The cranberry extract is a commercially-available food ingredient. Rinsing with the cranberry extract poses no foreseeable risks to your health. The saliva collection procedure poses no foreseeable risks to your health. Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others.

Therefore, your genetic information potentially could be used in ways that could cause you or your family economic stress. There are state and federal laws that protect against genetic discrimination. A federal law, the Genetic Information Nondiscrimination Act makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. The genetic information collected in this study is specific for taste genes that are not considered risk factors for major diseases. Thus, by participating in this study, the risks of harm to your employability or your ability to obtain healthcare insurance is extremely low.

Are there any benefits to me if I choose to take part in this study?
Although you will receive no direct benefits from participating in this study, this research will benefit society by providing a better understanding of the relationship between taste and oral health.

What are my alternatives if I do not want to take part in this study?
Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
The results of the study might be share in aggregate form with participants at the end of the study by request.

Will there be any cost to me to take part in this study?
There are no costs to you for participating in the study.

Will I be paid to take part in this study?
The screening is an unpaid session. At the completion of the study, you will receive a single payment of $60.00 in the form of a gift card. Payment will be pre-rated if you do not complete all the sessions.

How will information about me be kept private or confidential?
The information collected in this study will be kept strictly confidential. 'Confidential' means that your name and the information collected about you will be linked by a code number, and the code number will be used to identify your data. All data will be kept in on a password protected computer in the PI's laboratory. Only research staff involved in this study or the Institutional Review Board (a committee that reviews research studies in order to protect research participants) at Rutgers University will be allowed to see the data, except as may be required by law. If a report of this study is published, or the results are presented at a professional conference, only group results will be stated. You will not be personally identified in any report of this research. All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.
The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards

- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

A description of this clinical trial will be available on 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.

What will happen to my information and biospecimens collected for this research after the study is over?
The biospecimens and information collected about you will only be used for this research. Your data will not be used by or distributed to investigators for other research studies.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled. You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Beverly J Tepper, PhD: Department of Food Science, Rutgers University, 65 Dudley Road, New Brunswick, NJ 08901.

Who can I contact if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the PI:
Dr. Beverly J Tepper, PhD: Department of Food Science, Rutgers University, 65 Dudley Road, New Brunswick, NJ 08901. Tel: 848-932-5417.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____