RUTGERS
Robert Wood Johnson Medical School

RUTGERS
New Jersey Institute for Food, Nutrition, and Health

CONSENT TO TAKE PART IN A RESEARCH STUDY

Effect of Concord Grape Polyphenol-Soy Protein Isolate Complex (GP-SPI) on Gut Microbiota

Principal Investigator: Diana Roopchand, PhD

Department of Food Science, Rutgers University
Institute for Food, Nutrition, and Health
61 Dudley Rd, Suite 220
New Brunswick, NJ 08901 Tel. 848-932-0248

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 effects of grape polyphenols (delivered as GP-SPI, a food ingredient/supplement) on: 1) intestinal bacteria (called the gut microbiota); 2) the molecules produced by these bacteria (called microbial metabolites) that may be detected in urine, feces, and/or blood; and 3) liver and kidney function. If you take part in the research, you will be asked to 1) abstain from certain polyphenol-rich foods (a list will be provided), 2) consume SPI for 5 days and GP-SPI for 10 days in water or a smoothie (personal blender will be given to keep), 3) take photos of food and drink consumed during study period (a digital food diary), 4) use provided kits to self-collect nine samples of stool and seven samples of urine, 5) use Bristol stool scale to provide description of stool characteristics, and 6) provide three blood samples. Your time in the study will take 17 days, including a screening and consent visit (45 min), 3 visits for blood sampling (20 min each), and 7 visits to bring in urine and stools samples and follow up with study staff (20 min). Possible harms or burdens of taking part in the study may be a bruise or bleeding at site of blood draw, and collection and storage of urine and stool samples may cause some discomfort. You will receive a copy of your blood results including glucose at no cost and a copy of your gut microbiota community analysis data. There are no other benefits. 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 all of 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 research study?
Dr. Diana Roopchand, PhD is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Diana Roopchand, PhD may be reached at Tel. 848-932-0248
Department of Food Science, Rutgers University
Institute for Food, Nutrition, and Health
61 Dudley Rd, Suite 220
New Brunswick, NJ 08901

The Principal investigator 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.

This study is funded in part by the National Institute of Health (NIH).

Why is this study being done?
This study is being done to determine whether oral supplementation with Concord grape polyphenol-soy protein isolate (**GP-SPI**) complex changes the bacteria in human gut and stool. Bacteria can metabolize grape polyphenols to produce metabolite compounds that may be detectable in blood, feces, and/or urine, therefore these will also be collected for analyses of these compounds.

Who may take part in this study and who may not?

You may participate if you are:

- Healthy male or non-pregnant female adult (overall health will be confirmed by a comprehensive metabolic panel blood test)
- Ages 18-35
- Body Mass Index of 18.8 - 29.9
- Have at least one bowel movement per day
- Agree to follow list of foods allowed and not allowed during wash-out and study period
- Able to provide written consent

You may not participate if you are:

- Current smoker or have smoked within previous 6 months
- Taking medications regularly (prescription, over the counter, supplements etc.)
- Treated with antibiotics during the past 6 months
- Have an allergy to soy or grapes
- Pregnant, trying to become pregnant or breastfeeding

Why have I been asked to take part in this study?
You are being invited to take part in the study because you meet the above inclusion and exclusion criteria

How long will the study take and how many subjects will take part?
This is a single site study. Thirty subjects will be enrolled in this 17-day study.

What will I be asked to do if I take part in this study?
Participation in this study includes the following according to the time schedule outlined below:

- Review study and inclusion/exclusion criteria
- Obtain consent
- Medical history

- Pregnancy test
- Height & weight
- Blood draw for CMP test
- Abstain (wash out period) from food items not allowed for over the 17 days of the study
- Collect stool sample (in provided collection kits with instructions) to be stored temporarily in your fridge, freezer, or at room temperature until brought to the lab for storage
- Provide description of stool sample using provided Bristol Stool scale chart
- Collect urine samples (in provided collection containers with instructions) to be stored temporarily in your fridge until brought to the lab for storage
- Fasting Blood Sample (2 tablespoons) on day -5, day 0, and day 11 of the supplementation period. You must not eat for 10 hours prior to blood draw
- Receive SPI packets for 5 days and GP-SPI packets for 10 days with instructions to mix one packet in ~240 mL (1 cup; 8 oz.) of water or in a smoothie containing foods from the allowed list of items. A personal blender (value ~$25) will be provided for you to keep
- Drink SPI solution before breakfast and dinner every day for 5 days
- Drink GP-SPI solution before breakfast and dinner every day for 10 days
- Maintain your usual diet except abstain from unallowed foods
- Keep daily food diaries and take digital photos of all foods (meals, beverages except water, and snacks) consumed from days -5 to 11 (16 days)
- Download the application WhatsApp on your smart phone to send photos of food and drink to study personnel with a brief description of items in the photo
- Lab Visits (20 minutes) to drop off stool and urine samples, pick up new GP-SPI packets and review food diary

Table 1. Schedule of events and sample collections

Days	Screen	-5	0	2	4	6	8	10	11
Informed Consent	X								
Incl/Excl Criteria	X								
Med. History	X								
Height &Weight	X								
Clinic Visit	X		X						X
Blood Draw	X		X						X
Urine Sample		X	X	X	X	X	X	X	
Stool Sample		1	2	1	1	1	1	2	
Urine Pregnancy	X								
SPI		Twice a day for 5 days	Break						
GP-SPI				Twice a day on days 1 - 10					
Food Diary		Daily up until blood draw on day 11							

What are the risks and/or discomforts I might experience if I take part in this study?

GP-SPI – there are no known risks to ingesting the study supplement. To minimize the risk of an allergic reaction the study excludes persons allergic to soy or grapes.

Blood Sampling – may cause a bruise or bleeding at the site. Infection at the site is rare. A total of 65 mL (about 4 Tablespoons) will be drawn during the course of the study. Healthy subjects can tolerate this blood loss without any side effects.

Urine and Stool samples - collection and storage may cause some discomfort.

Confidentiality - Future studies on de-identified samples may include genetic testing (e.g. nutrigenomics, to study interaction of nutrition and genes). Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further, patterns of genetic variation also can be used by agencies to identify a person or his/her blood relatives (for example, to establish relationships between parents and their children).

Reproductive Risks of Harm - Soy protein and dietary polyphenols are often consumed as part of a normal diet; however, in case of pregnancy within the 17-day study period, the risk of GP-SPI to a newly formed embryo/fetus is unknown. This study will not include pregnant subjects and a urine-based pregnancy test will be performed to confirm inclusion of only non-pregnant participants*.* If you become pregnant during the course of this study, you should notify the study personnel of this fact as soon as possible, since the risks to the fetus or to yourself are unknown.

Are there any benefits to me if I choose to take part in this study?
You will receive a copy of your CMP blood test results including glucose at no cost. You will receive a copy of your gut microbiota profile after all data is analyzed.

What are my alternatives if I do not want to take part in this study?
This study is being conducted for research purposes only. You may choose not to take part in this study. You will not receive other benefits from taking 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 course of 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?
If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. You will receive a copy of your CMP blood test results including glucose at no cost. You will receive a copy of your gut microbiota community analysis data after all study data is analyzed.

Will there be any cost to me to take part in this study?
No

Will I be paid to take part in this study?
You will receive $5 for each blood, stool, and urine sample delivered over days -5, 0, 2, 4, 6, 8 & 10, a total of $90). An additional $110 on Day 11 will be received for providing all samples (2 blood samples, 9 stool and 7 urine samples), completed Bristol stool scale chart, digital and written food diaries sent via WhatsApp, and completion of all study visits, otherwise only $5 per sample will be given. The total amount that you will receive if you complete the study is $200. You will receive payment on your last study visit.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.
Your personal identity, including your name and other identifiers, will be kept confidential. You will have a code number and your actual name will not be used. Only study personnel will be able to link the code number to your name and will keep this information for six years after study completion.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers will use this Certificate to legally refuse to disclose any information, documents or biospecimens that may identify you from disclosure, including a court order. This means that research material collected about you for this study will not be released to anyone who is not connected with this study unless:

- you request or consent to its release;
- a law requires its release (such as reporting communicable diseases or child abuse to State agencies);
- it is used for other scientific research, as allowed by federal regulations protecting subjects; or
- it is requested by the U.S. federal or state agency sponsoring the research that is needed for auditing or program evaluation or to meet the requirements of the Food and Drug Administration (FDA)."

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.

Who may use, share or receive my information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- 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
- National Institute of Health (NIH)

What will happen to my information or biospecimens collected for this research after the study is over?
The stool, urine, and blood samples you provide during the study will be coded to protect your identity and then stored in laboratory freezers until samples can be processed. Samples will be analyzed using state-of-the art science to better understand how dietary compounds (like grape

polyphenols) affect the gut microbial community (metagenomics analyses) and how the microbiota or host cells may process these compounds to metabolites that are then found in blood, feces, and urine (metabolomics analyses). Leftover de-identified samples will be stored for use in future studies. If you do not agree to future use of samples, you cannot participate in this study.

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. Diana Roopchand at roopchand@sebs.rutgers.edu.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I call if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call:

Dr. Diana Roopchand, PhD
Tel. 848-932-0248
Department of Food Science, Rutgers University
Institute for Food, Nutrition, and Health
61 Dudley Rd, Suite 220
New Brunswick, NJ 08901

If you have questions about your rights as a research subject, you can call the IRB Director at New Brunswick/Piscataway ArtSci IRB (832)235-2866 or the Rutgers Human Subjects Protection Program at (973) 972-1149.

Data Sharing

We would like to share the microbiome and metabolome data generated from the samples you provide with other researchers. The shared data would not include identifiers, like your name, date of birth, or where you live. If you agree, we will deposit your de-identified data into databases at the National Institutes of Health (NIH) https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/ . The results of any computational analyses using your data will not be returned to you because the researchers won't know who you are or how to reach you. The risk of connecting your data to you or your health information is very small. There is no direct benefit to you for placing your information in the repository. Allowing researchers to use your data may help other people in the future. Your decision for data sharing will not affect your participation in the main study.

Please initial one: (If there are no initials data will not be shared)

_____ I grant permission for you to enter my de-identified data from this study into the NIH Databases.

_____ I DO NOT grant permission for you to enter my de-identified data from this study into the NIH Databases.

AGREEMENT TO PARTICIPATE

1. 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:_____

Subject Signature:_____ Date:_____

2. 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 (printed name):_____

Signature:_____ Date: _____