**California State Polytechnic University, Pomona**
**Informed Consent Form for Research Involving Human Participants IRB #23-06**

*You are being invited to participate in a research study, which the Cal Poly Pomona Institutional Review Board (IRB) has reviewed and approved under protocol IRB#23-06, for conduct by the investigators named here. This form is designed to provide you-as a human subject-with information about this study. The Investigator or his/her representative will describe this study to you and answer any of your questions. You are entitled to copy of this form, if you would like one. If you have any questions or complaints about the informed consent process of this research study or your rights as a subject, please contact the Compliance Office within Cal Poly Pomona's Office of Research at (909) 869-4215.*

## The Effects of Freeze-Dried Whole Grape Powder on Chronic Disease and Cardiovascular Risk Factors, Hunger, Satiety, and Body Composition in Free-Living People-a Pilot Study (aka The Grape Study) IRB #23-6

Primary Investigator: Dr. Bonny Burns-Whitmore; Co-Primary Investigator: Dr. Erik Froyen

**The purpose of the study:** To determine if grape consumption: 1) decreases fasting blood glucose, total cholesterol, LDL, and triacylglycerides; 2) decreases body composition risk (%body fat); 3) increases body lean tissue; 4) decreases inflammation (hs-CRP levels and TNF-alpha levels); 5) increases satiety and decreases hunger; 6) lowers blood pressure.

**Procedures:** Dr. B. Burns-Whitmore (bburnswhitmo@cpp.edu) and Dr. Erik Froyen (ebfroyen@cpp.edu) from California State Polytechnic University, Pomona will be conducting a research study using freeze-dried grape powder (equivalent to about 2/3 cup of fresh grapes) and a look-like substitute to determine how grapes affect cardiovascular risk factors such as body composition, inflammation, blood lipids, weight, and blood pressure. We will also be looking at satiety/hunger and collecting (3) 24-hour recalls.

**Commitment:** If you agree to be a part in this study, you will be asked to sign this consent form and fill out a screening questionnaire. After the forms are received by the researchers, the researchers will determine if you qualify for the study. If you meet the requirements for the study, we will ask you to make an appointment to visit building 2-119 to have your body composition and height measured, and then go to the Student Health Center to have your weight, blood pressure, and have your blood drawn. This will take about 20-25 minutes. We will ask you to do this at the beginning and end of treatment 1 (Fall 2023) and at the beginning and end of treatment 2 (Spring 2024). Each of these (4) visits may take between 20-25 minutes. You will be asked to meet with the researchers weekly, to pick up your grape powder (which will take only about 5 minutes). We will also ask you to do (3) randomized 24-hour recalls and (3) satiety questionnaires each treatment, which may take about 30 minutes each to perform. Each treatment (1 &2) will be 8 weeks each with the winter break between each treatment. Therefore, you will participate in both Fall 2023 and Spring 2024 semesters.

**Compensation:** You will receive $150.00 and a certificate of completion when you finish both 8-week arms of the study. You may refuse to participate in this study at any time. All participants completing the study will provided a certificate of completion, which may be used to provide confirmation to graduate programs/internships by you, the participant, that you have been involved in the research process.

**Possible Risks:** This study is a minimal risk study. However, there might be a discomfort or annoyance/tediousness in providing your diet and activity records. You have the right not to provide your diet/activity information or answer the questions if you do not want to. We have asked you on the screening form if you are allergic to grapes (a very rare allergy), grape products, or cross-reactive allergies such as peach, tree nuts, mustard, mulberry, cabbage, figs, kiwi, bananas, melon, apple, and other foods in terms of the lipid-transfer protein contained in grapes, however, the clinical significance of these cross-reactivities has not been

clearly established. There is always a chance that you can develop an allergy to either treatment or have a cross-sensitivity reaction. This can be mild, such as hives, skin rashes, or mild swelling on the lips or tongue, or lead to a severe reaction that may interfere with breathing (anaphylaxis). Additionally, a blood draw may lead to lightheadedness or fainting. It may also cause bruising, prolonged bleeding, and infection at the site where the blood was drawn. To minimize these risks, we will utilize professional phlebotomists, swab the site of the blood draw with alcohol to disinfect the area, use disposable sterile needles and tubes to collect blood, and apply pressure to the site following the blood draw to minimize bruising. To protect against infection, we will also provide a bandage if requested. It is important to know that these blood tests performed in the study are strictly for research purposes and not for diagnostic purposes.

Please initial here _____ if you have a metal implant, monitoring equipment, or non-removal body piercings. We ask this because those that do have any of these could have a severe adverse issue occur including death, since the Tanita does send a small electrical current through the body, which may disrupt devices or cause injury. Having these implants/non-removal body piercings will not cause you to be excluded from the study, but you will not be permitted to be assessed by the Tanita Body Impedance Scale.

**Confidentiality:** All collected data will be saved onto a password protected computer. Your other forms will be stored in a locked file in a locked office. Your name will be replaced by a code number and any documents that can be attributed to your name and this code number will be destroyed after the study. We may share the results of this study with other researchers however; they will not know who you are. The results of this study, in either an anonymous or a summarized format, will be published or presented at conferences.

**Costs:** There will be no cost to you, except for transportation costs to and from Cal Poly Pomona. We will supply the freeze-dried grape powder and the taste/look-a-like control at no charge to you. Any questions about this research can be addressed to Dr. Erik Froyen at ebfroyen@cpp.edu or Dr. B. Burns-Whitmore, at bburnswhitmo@cpp.edu.

**Consent:** This informed consent form has discussed the risk and benefits of this research. I understand that by consenting to being a subject in this study that I acknowledge these risks and benefits. It is unlikely that severe injury will result from participation in this research, however, if any study-related activities result in an injury, treatment will be made available including first aid and referral for emergency care as needed. The cost for such care will be billed in the ordinary manner to you, or your insurance company. Emergency medical care is not available on-site. If you should sustain an allergy to the food items as a result of this research, no other provisions have been made for financial payments or other forms of compensation. No reimbursement, compensation, or free medical care is offered by Cal Poly Pomona University. If you think that you have suffered an injury related to your participation in this study, contact Dr. Burns-Whitmore or Dr. Froyen or the Research Compliance Office. If you wish to report a problem regarding violation of research subject rights, please contact the Compliance Office at (909) 869-4215. By signing below, you certify that you are 18 years or older, not pregnant or nursing, and agree to participate in this study.

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Name Signature Date

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Investigator Name Signature Date