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Document: Protocol with Informed Consent Form

Study Title: Impact of Haskap Berries on Recovery from High Intensity Resistance Training

Document Date: 9/26/2025

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SUBJECT CONSENT FORM FOR PARTICIPATION IN HUMAN RESEARCH AT MONTANA STATE UNIVERSITY

Study Title: Impact of Haskap Berries on Recovery from High Intensity Resistance Training

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IRB Protocol Number: 2025-2138

Why are we doing this study?

You are being asked to participate in a research study to learn more about how the Haskap berry can impact the recovery process from intense resistance training. Haskap berries are very high in several compounds that function as antioxidants, such as polyphenols and vitamin C, which have many health promoting effects. For example, antioxidants lower inflammation and oxidative stress, which is known to cause damage to cells, proteins, and DNA. Oxidative stress is a result of excess free radicals, which are unstable molecules that can be created, along with inflammation, during intense exercise. This combination of excessive harmful byproducts in the body can cause soreness and decrease muscle performance experienced after a workout. However, the antioxidants in foods have the ability to neutralize free radicals that are produced and may reduce the time to recover from exercise. Investigating how a person's body responds to intense exercise with and without high antioxidant berries may help us obtain a better understanding of how to most effectively use Haskap berries to improve recovery from intense exercise.

What is the purpose of this study?

The purpose of this study is to determine how certain food items affect oxidative stress, inflammation, and performance recovery from exercise induced muscle damage. Specifically, we are asking the following questions:

1. Do Haskaps speed the recovery of oxidative stress and inflammation markers after an intense lower body workout in resistance trained adults?
2. Do Haskaps speed the recovery of performance measures after an intense lower body workout in resistance trained adults?
3. The data collected in this investigation may also be used to ask additional questions not yet identified. For example, we may use the stored samples to evaluate how the blood metabolites of participants differ before and after intense exercise. These additional questions are called secondary analyses.

Please note that no genetic analysis will be conducted and racial and ethnic differences among participants will not be used in any secondary analyses.

If we learn how polyphenols influence recovery from exercise and how this might impact performance in activities of daily living and sports, then we can use that information to do more research to improve recovery from strenuous exercise.

Why am I being asked to participate in this study?

You are being asked to be in this study because you are 18-35 years old, have two or more years of self-reported barbell squat experience and are currently squatting at least once a week. **The first step in the study will be to screen you to see if you meet the criteria. If you do, then you may be enrolled in the study.**

You cannot participate in this study if you have a food allergy that may include Haskap berries or food colorings, or if you have a body mass index (measured based on height and weight) under 18 or over 40 kg/m^2. You cannot participate if you are pregnant, smoke cigarettes, have had a lower extremity injury in the last year, or take anti-inflammatory, weight loss, anabolic steroids, testosterone, or other drugs that may interfere with the measures of the study. Additionally, health conditions that may influence metabolic or inflammation measures in the study such as type 1 or type 2 diabetes or hypo-/hyperthyroidism will exclude you from participating in the study. You may also be excluded from the study if you follow a special diet including vegan, vegetarian, low carbohydrate, or ketogenic. Lastly, you may be excluded from the study if you regularly consume any of the following products: tart cherry juice, pomegranate juice, or 1 or more cups of acai or other berries per day.

If you are eligible to be in the study after we complete the screening and choose to participate in the study, then you will be enrolled in the study to have measures taken before and after you consume either juice or a placebo. The placebo in this study is a color, flavor, and carbohydrate matched beverage was developed in our lab after numerous testing trials to ensure it is similar to Haskap juice. Whether you receive the juice or placebo will be randomly assigned. Each participant has equal opportunity to be in either group. A third-party researcher is responsible for the beverage production and random assignment of beverages to ensure investigators do not know which beverage is given to each research participant. This is a double-blinded study; neither you nor the investigators will know which beverage you are consuming.

What will I do if I take part in this study?

Participation is voluntary. If you agree to participate then you will be asked to do the following things:

SCREENING & FAMILIARIZATION VISIT. This visit will take 1.5-2 hours and take place in the Nutrition Research Laboratory. The screening portion of the visit will include the following activities:

1. **Informed consent (this document).** Researchers will go through the informed consent document with you, explain details of the study, and encourage you to ask any questions. You will be given a copy of this document for your own records. If you want to participate in the study, then you will give written informed consent to participate in the study by signing this document.
2. **Confirm eligibility and exclusion criteria.** You will be asked to confirm your age, lifting experience, injury history, history of supplement use, current diet practices, and date of last lower body workout to determine your eligibility for this study.
3. **Body size measurements.** Researchers will measure your height and weight. You will remain clothed during these measurements; however, you will be asked to remove extra clothing such as sweaters and shoes.
4. **Confirm last workout.** Lower body workouts should cease at least 48 hours before this visit. If the participant has completed a lower body workout within 48 hours, their enrollment in the study will be postponed.

These results will be used to determine if you meet the criteria for the study. If you do not meet the criteria, then your participation in the study will be done. If you meet the criteria and choose to continue with the study, then we will continue to the familiarization portion of the visit. If you meet the criteria of the study but have performed a lower body workout within 48 hours, your enrollment in the study may be postponed.

The familiarization portion of the visit will follow the screening procedures and will include the following activities:

1. **Sleep questionnaire**. Complete a 5-question survey that asks questions about the duration and quality of your sleep from the night before. This data will help us understand your recovery from the exercise.
2. **Soreness questionnaire**. You will be asked to stand up and sit down with your hands on your hips then draw a line on a 10 cm pain scale (0: no pain - 10: worst pain possible) to indicate the level of soreness you are experiencing. Soreness will be tracked throughout the study as a subjective measure of recovery.
3. **Blood collection.** Blood will be collected before exercise. Standard procedures for collection of blood from a forearm vein will be used to collect blood. Blood samples will allow us to measure inflammatory and muscle damage markers, metabolites (a wide variety of small molecules relating to all the biochemical processes in your body), and other biomarkers related to the recovery process.

Blood specimens will be labeled according to the participant's number, the timepoint the specimen comes from. Samples will be stored in the -80° freezer in the Nutrition Research Lab until analyzed.

4. **Warm up.** You will complete a warmup consisting of 5 minutes of self-selected low intensity pedaling on a stationary bike and dynamic stretches (10 lateral squats and 10 walking lunges).
5. **Intensity Determination Tests.** Results of these exercises (barbell back squat and maximal isometric contraction of the quadriceps) will be used to determine the intensity that you will exercise at for the workout visit.
    a. **Barbell squat.** Safeties will be set at an appropriate height and spotters will be present. You will start your warmup sets with the unloaded barbell then at 30-50% of your self-reported 1RM. After each successful 3 rep attempt, the weight will be increased by 2.5-10% each set. You will rest 2-5 minutes between sets. The greatest weight you can complete for 3 repetitions without assistance and with adequate depth will be taken as your 3-repetition maximum. You are able to stop the testing at any point in time or if you feel you have completed the highest possible weight. This weight will be used to determine your working weight for the workout visit.
    b. **Maximal isometric contraction.** Maximal contraction of the quadriceps will be analyzed on an isokinetic dynamometer (Biodex) where you will be seated upright with your back against a pad. You will start with your knees bent at 90 degrees and shins resting behind a padded bar just above your ankles. You will be cued to straighten your leg by pushing your shin upward on the padded bar. Your quadriceps contract to perform this movement. The bar will stop at 60 degrees of flexion and you will receive verbal encouragement to push as hard as you can against the bar for 2 seconds. You will do this 2 times resting 10 seconds between reps.

To monitor for potential injury or overexertion, a trained researcher will be present to observe all exercises in real time. You will be instructed to stop immediately if you experience any pain, dizziness, shortness of breath beyond expected exertion, or signs of fatigue that compromise proper form. Verbal check-ins will be conducted before, during, and after each set to assess comfort and safety.

After the completion of the Screening and Familiarization Visit, you will be given either Haskap juice or a placebo to begin juice consumption and the 11-day dietary intervention.

11-DAY DIETARY INTERVENTION. The dietary intervention and supplementation will last a total of 11 days. You will be asked to consume either Haskap juice or a placebo. The placebo in this study is a color, flavor, and carbohydrate matched beverage which was developed in our lab after numerous testing trials to ensure it is similar to Haskap juice. You will begin after the Familiarization Visit and continue through the final testing visit. There will be a 1-week period where you will be asked to follow the dietary intervention before the workout visit.

1) **Juice pick-ups from the Nutrition Research Laboratory.** Juice will be given to you for the entirety of the dietary intervention at the completion of the Familiarization Visit.
2) **Juice consumption.** The determined dose (mL/day) will be divided into two doses to be consumed 12 hours apart (morning and evening dose). Juice dosage will be determined based on relative body weight (kg) and will be person dependent.
3) **Daily logs to verify consumption of research juice.** A paper log sheet will be given to participants on a twice daily basis and asked to respond “yes” or “no” to indicate whether you consumed the research juice that day. While we hope you will drink all the juice, we understand you may not be able to do that, and we ask you to report when you do.
4) **Adherence to low polyphenolic diet**. You will be provided with a comprehensive list of foods that you need to avoid eating during the 11-day intervention because they contain similar compounds to those found in Haskap berries. This includes foods such as red or purple berries and fruits or juices. You will be asked to limit your caffeine intake from coffee and tea consumption to one 8 oz serving per day.
5) **Diet Adherence questionnaire**. Participants will be asked to respond to questions regarding their adherence to the diet guidelines provided. If you consume a food or beverage from the prohibited food list provided, record the amount and type consumed on this form. **You are not disqualified from the study if this occurs.** Please continue to take your supplements and follow the diet guidelines.
6) **Cease all workouts 48 hours before the workout visit.** Participants will be asked to not engage in any intense physical activities outside of the study on days 6-11 of the supplementation period.

WORKOUT VISIT. The Workout Visit will occur on day 8 of the supplementation period and take about 2 hours. This visit requires a final blood draw 8 hours after the completion of the workout and will include the following activities:

1. **Sleep questionnaire**. Complete a 5-question survey that asks questions about the duration and quality of your sleep from the night before. This data will help us understand your recovery from the exercise.
2. **Soreness questionnaire**. You will be asked to stand up and sit down with your hands on your hips then draw a line on a 10 cm pain scale (0: no pain - 10: worst pain possible) to indicate the level of soreness you are experiencing. Soreness will be tracked throughout the study as subjective measure of recovery.
3. **24-hour diet recall.** A 24-hour diet recall will outline the types and quantities of foods and beverages consumed the day prior. You will be asked to repeat a similar caloric and macronutrient intake for the three testing days following.
4. **Measurement of muscle and fat tissue using bioelectrical impedance analysis.** This test simply involves standing on a scale with your feet and hands on sensors for a few seconds. A very low electrical current that you cannot feel and that is not dangerous is transmitted and received across the sensors. The technology is commonly used in a variety of settings such as gyms and health screenings, but the instrument that we will use is more sophisticated in being able to estimate muscle and fat tissue in different regions of your body which can be used as a potential explanatory factor for variation in performance.
5. **Blood collection.** Blood will be collected before exercise (baseline), immediately after the workout, and 8 hours after completion of the workout. Standard procedures for collection of blood from a forearm vein will be used to collect blood. Blood samples will allow us to measure inflammatory and muscle damage markers, metabolites (a wide variety of small molecules relating to all the biochemical processes in your body) and other biomarkers related to the recovery process. Blood specimens will be labeled according to the participant's number, the timepoint the specimen comes from. Samples will be stored in the -80° freezer in the Nutrition Research Lab until analyzed.
6. **Warm up.** You will complete a warmup consisting of 5 minutes of self-selected low intensity pedaling on a stationary bike and dynamic stretches (10 lateral squats and 10 walking lunges).
7. **Vertical jump test.** Vertical jump will require you to jump as high as possible on force plates. You will be given two practice jumps to familiarize yourself with the force plates. After the practice jumps, you will have three test counter movement jumps. The highest jump will be used to assess vertical jump performance. This will be evaluated before and immediately after the workout.
8. **Maximal knee extension test.** Maximal contraction of the quadriceps will be analyzed on an isokinetic dynamometer (Biodex) where you will be seated upright with your back against a pad. You will start with your knees bent at 90 degrees and shins resting behind a padded bar just above your ankles. You will be cued to straighten your leg by pushing your shin upward on the padded bar.

Your quadriceps contract to perform this movement. The bar will stop at 60 degrees of flexion and you will receive verbal encouragement to push as hard as you can against the bar for 2 seconds. You will do this 2 times resting 10 seconds between reps.

a. Vertical jump and Maximal knee extension will be evaluated before and immediately after the workout.

9. **Workout.**
    c. **Barbell squats.** Safeties will be set at an appropriate height and spotters will be present. You will work up to your working weight using predetermined warmup sets. Once reaching 70% of your estimated 1RM found in the Familiarization Visit, you will complete two sets of one rep to determine a maximal velocity at your working weight. You will then be asked to perform a set of 3 repetitions of squats on the top of every minute for 10 minutes. Repetitions must be completed consecutively with minimal time between reps within a set.
    d. **Leg Extension**: You will work up to the weight determined during the Familiarization Visit using predetermined warmup sets. You will then perform as many reps as possible at this weight for 3 sets. Failure to complete a rep will end each set.

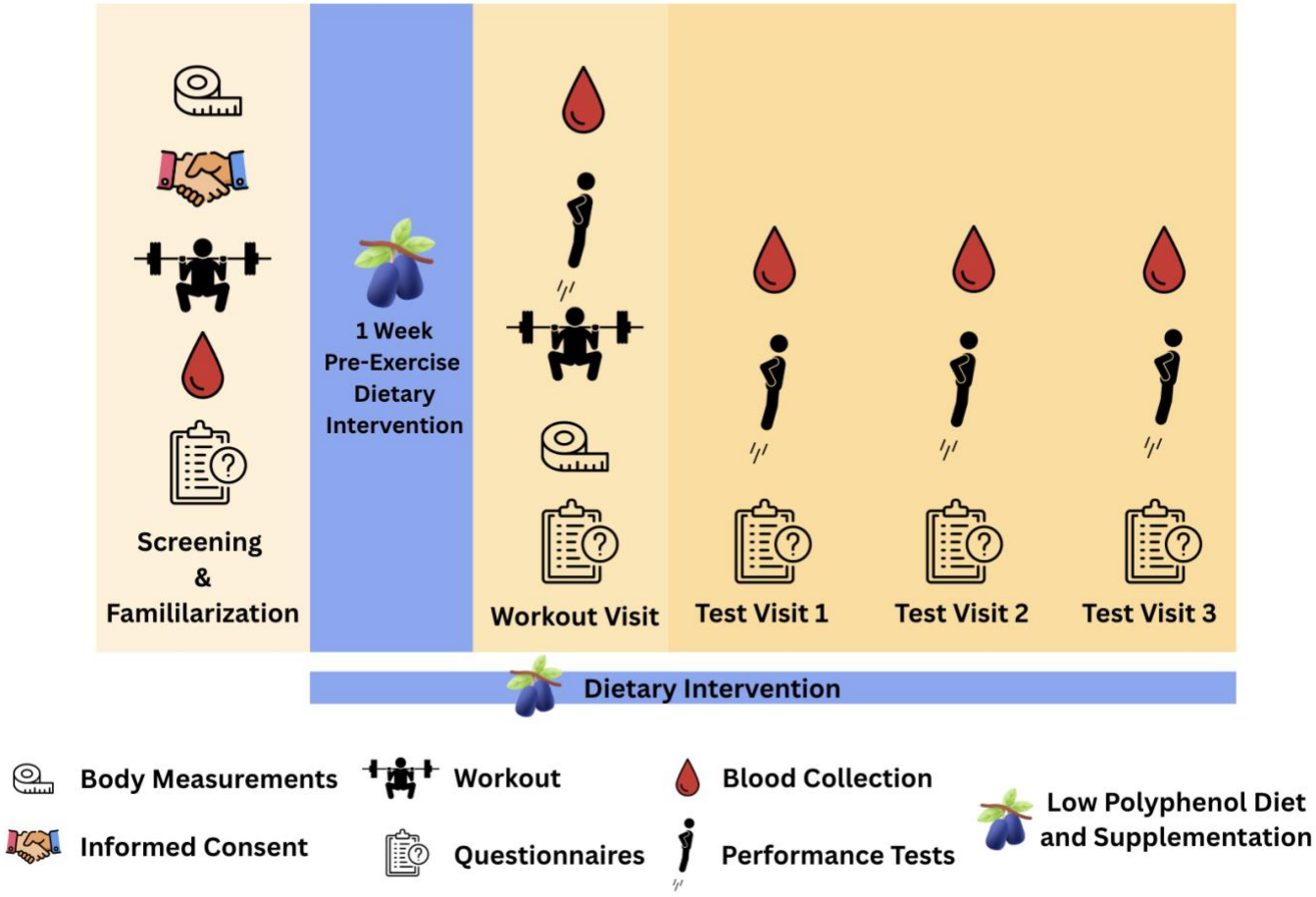
To monitor for potential injury or overexertion, a trained researcher will be present to observe all exercises in real time. You will be instructed to stop immediately if you experience any pain, dizziness, shortness of breath beyond expected exertion, or signs of fatigue that compromise proper form. Verbal check-ins will be conducted before, during, and after each set to assess comfort and safety. Standardized rest periods and warm-up procedures will be implemented to reduce risk, and you may withdraw from the test at any time without penalty.

TESTING VISITS 1-3: Testing Visits 1 through 3 will take place on supplementation days 9-11 and take 45 minutes to 1 hour. These visits will include questionnaires and performance tests.

1. **Sleep questionnaire**. Complete a 5 question survey that asks questions about the duration and quality of your sleep from the night before. This data will help us understand your recovery from the exercise.
2. **Soreness questionnaire**. You will be asked to stand up and sit down with your hands on your hips then draw a line on a 10 cm pain scale (0: no pain - 10: worst pain possible) to indicate the level of soreness you are experiencing. Soreness will be tracked throughout the study as subjective measure of recovery.

3. **24-hour diet recall.** A 24-hour diet recall will outline the types and quantities of foods and beverages consumed the day prior.
4. **Blood collection.** Blood will be collected before exercise. Standard procedures for collection of blood from a forearm vein will be used to collect blood. Blood samples will allow us to measure inflammatory and muscle damage markers, metabolites (a wide variety of small molecules relating to all the biochemical processes in your body) and other biomarkers related to the recovery process. Blood specimens will be labeled according to the participant's number, the timepoint the specimen comes from. Samples will be stored in the -80° freezer in the Nutrition Research Lab until analyzed.
5. **Warm up.** You will complete a warmup consisting of 5 minutes of self-selected low intensity pedaling on a stationary bike and dynamic stretches (10 lateral squats and 10 walking lunges).
6. **Vertical jump test.** Vertical jump test will require you to perform 3 maximal counter movement jumps on force plates. You will be given two practice jumps before jumping as high as possible for 3 repetitions. The highest of 3 jumps will determine your maximal vertical jump.
7. **Maximal knee extension test.** Maximal contraction of the quadriceps will be analyzed on an isokinetic dynamometer (Biodex) where you will be seated upright with your back against a pad. You will start with your knees bent at 90 degrees and shins resting behind a padded bar just above your ankles. You will be cued to straighten your leg by pushing your shin upward on the padded bar. Your quadriceps contract to perform this movement. The bar will stop at 60 degrees of flexion and you will receive verbal encouragement to push as hard as you can against the bar for 2 seconds. You will do this 2 times resting 10 seconds between reps.
8. **Barbell squats.** Safeties will be set at an appropriate height and spotters will be present. You will work up to your working weight using predetermined warmup sets. Once reaching 70% of your estimated 1RM found in the Familiarization Visit, you will complete two sets of one rep to determine a maximal velocity at your working weight. You will then be asked to perform a set of 3 repetitions of squats on the top of every minute for 3 minutes.

Completion of the study will take 9-14 days, depending on the visit scheduling. Total time spent in the Nutrition Research Laboratory is 7-9 hours and a total of about 21 teaspoons of blood samples will be collected throughout the study. Below is a visual overview of the study:



Risks: There are side effects and risks involved from having blood drawn or doing certain activities. These side effects are often called risks, and for this project, the risks are:

1) Approximately 14 milliliters (about 0.5 fluid ounces) or 3 teaspoons of blood will be removed one time during the Familiarization Visit, 3 times during the Workout Visit and once at each of the 3 Testing Visits. A trained phlebotomist or clinician will be drawing the blood. You may experience momentary pain when a needle goes into your arm. In about 10% of cases, a small amount of bleeding under the skin will produce a bruise (hematoma). The risk of temporary clotting of the vein is about 1%, while the risk of infection or hematoma, or significant external blood loss is less than 1 in 1,000. Some people may feel lightheaded, nausea, or perhaps faint.
2) This diet may cause gastrointestinal disturbance (flatulence or other discomfort).
3) There are a total of 5 squat exercise tests, 2 leg extension exercise tests, 4 maximal quadricep contraction tests and 4 vertical jump tests. These exercise tests could make your legs and body feel fatigued. You may experience muscle

soreness and general discomfort. Risks of performing heavy squats include injuries to the back, knees and hips, however, the risks are no different from resistance training on your own. The squat rack will have the safeties set at an appropriate height for each participant and the researchers that will be present hold one or more of the following certifications: Certified Strength and Conditioning Specialist (CSCS), National Academy of Sports Medicine (NASM), CPR, and AED certifications. You can stop the exercise tests at any time.

Benefits: You may gain some benefits by participating in this study, such as information about your body composition. No other benefits are promised to you.

Use of blood samples for future studies:

The samples collected from you as part of this study may be valuable for future studies that are not yet planned. For example, we may learn new things in this study that spark new research questions that may be answered by analyzing the samples for things not currently planned in the current study. This will not include your DNA for genetic analysis because your DNA is not being collected in the present study. If these opportunities arise, we would like to do more research using the samples collected in this study. This will not involve any extra procedures beyond those described for this study. The samples that will be stored for future analysis will be coded with a participant number, but there will be no way to connect the samples with your identity. Samples and coded information may be stored for five years after study completion, after which it will be shredded and destroyed.

The samples will be owned and controlled by the principal investigator of this study, Dr. Mary Miles, and they will be stored in a freezer in her laboratory. Information linking your name to the coded samples will be destroyed at the end of the current study. You have the right to refuse consent to having your samples stored for future studies. This will not prevent you from participating in the current study. If you consent to the use of your samples in future studies, then you will not be able to withdraw your consent once the information linking your name to your coded samples is destroyed because we will have no way of knowing which samples are yours at that time. The samples may be stored until Dr. Miles leaves Montana State University. Dr. Miles will be the only researcher with authority to allow use of the samples if other investigators request access to the samples for future studies. You will not receive any information on data from your samples in future studies because there will be no way to link you to the samples. While it is not known what the future uses of these samples will be, some examples of future uses might be to measure new health biomarkers in the blood.

Compensation: If you are enrolled in the study, you will receive up to $60 upon completion of the study. You may withdraw from the study at any time. If you choose not to complete the study, then the amount of money paid to you will be prorated depending

on how much of the study you have completed ($15 for the familiarization visit, $15 for the workout visit, and $10 for each testing visit 1-3). Compensation is funded by the Kreighbaum Endowment.

Freedom of Consent: You have the right to withdraw from participating in the study at any time with a no questions asked policy. You may withdraw in writing (to Mary Miles at mmiles@montana.edu), over the phone (to Mary Miles at 406-994-6678), or in person. If you withdraw, you will not lose any benefits you incurred up to the time of withdrawal. Your participation in this study is completely voluntary.

Funding: This study is funded by the USDA Agricultural and Food Research Initiative and the Kreighbaum Endowment.

Please ask any questions: You are encouraged by the researcher to ask any and all questions you may have, as well as address any concerns about the study. The researcher will answer your questions as fully and as accurately as possible. Your peace of mind and comfort in the study is of utmost importance to the researchers.

Confidentiality: Names and contact information will be collected during the study, although all data and information received from you for this study will be kept completely confidential. You will be given a subject identification number that will be used to describe all the data. This data will be kept locked in a file cabinet in the Nutrition Research Laboratory. Any files linking you to the study will be destroyed after the completion of this study. Data from this project could be published in scientific journals and public data repositories, but you will be deidentified and will remain confidential. If you withdraw from the study at any time, all your information will be deleted from the study records, and you will not be contacted again. There are no penalties for withdrawing from the study.

Statement of Compensation: In the event your participation in this research supported by USDA AFRI results in injury to you, referral(s) to appropriate health care (Student Health Services, Bozeman Deaconess Hospital, your health care provider ,or calling 911) will be available; however, there is no compensation available from MSU for injury. Further information may be obtained by calling Mary Miles at 406-994-6678, or emailing her at mmiles@montana.edu.

Other questions regarding this study: Any other questions you may have regarding your rights as a participant may be answered by the chairman of the Human Subjects Committee, Mark Quinn. He can be reached at 406-994-4707 or mquinn@montana.edu.

STATEMENT OF AUTHORIZATION

Study Title: Impact of Haskap Berries on Recovery from Exercise-Induced Muscle Damage

AUTHORIZATION: I have read the above and understand the discomforts, inconveniences, and risk of this study. I, (name of subject), agree to participate in this research. I also agree that my health information can be collected and used by the researchers and staff for the research study described in this consent form. I understand that I may later refuse participation and withdraw from the study then. I have received a copy of this consent form for my own records.

Signed: _____Date:_____

Investigator:_____ Date:_____

Do you give us permission to use your blood or tissue for future research?
Please indicate if you agree to let us use your blood or tissue samples for future research. You do not have to give permission to use your blood or tissue samples for future research to participate in other parts of this study. Please ask questions if you do not understand why we are asking for your permission to use your samples for future research.
I agree to allow use of my blood or tissue sample for future research. *Please check Yes or No.*

- ▢ Yes – Please sign: _____Date:_____
- ▢ No