*This sample is for researchers to use as a guide in developing their study materials. Instructions to the researchers are written* *in* ***[square brackets in bold italics]*** *and should be deleted. Instructions that are* *in* ***[square brackets, bold italics, and are blue]*** *need to be replaced with details specific to the study and changed to* black, un-bolded, un-italicized*, and removed from square brackets before uploading the material to the research ethics application.****Please also delete this instructional paragraph.***

**\*\*Please review the Guide to Creating an Information Letter and Consent Form for additional details\*\***

Study Title: ***[Insert study title]***

Student Investigator: ***[insert name, University of Waterloo email address]***

Faculty Supervisor: ***[insert name, phone, University of Waterloo email address]***

Collaborators: ***[insert name of collaborator from organization]***

This letter explains what the study is about, possible risks and benefits, and your rights as a research participant. You may print/save a copy for your records. If you do not understand something in the letter, please ask one of the investigators before consenting to participate.

## Study Purpose:

Amino acids play an important role in human metabolism. In aging individuals and in some diseases, certain amino acids, such as glutamate, are at lower-than-normal levels. Glutamate has a central role in providing energy and maintaining normal blood sugar (glucose) levels. To better understand the changes seen in glutamate with disease, we are developing a method to examine how glutamate affects energy and carbohydrate metabolism. We will be using a nutritional approach to raise the body’s glutamate levels with monosodium glutamate (MSG) supplementation and raise blood glucose levels with a carbohydrate drink. By changing the normal levels of glutamate and glucose in the blood, we can evaluate how the body’s hormones respond, which can provide us with preliminary information about the role of glutamate in energy metabolism.

## Study Procedures Involved for All Participants:

We will be studying 10 healthy individuals (up to the age of 35). If you participate, you will be involved in 4 different sessions. You will be asked to complete a physical activity questionnaire, a food diary and follow the same diet prior to each of the study sessions.

For each of the sessions, you will be asked to come to the University of Waterloo after an overnight fast. Upon arrival, a research assistant will take your weight and height.

During a session, you will be asked to consume: a) carbohydrate drink + placebo gelatin capsules, b) flavoured water + placebo gelatin capsules, c) carbohydrate drink + MSG gelatin capsules, or d) flavoured water + MSG gelatin capsules. The order for these sessions will be determined by chance (i.e., like drawing a piece of paper with a number on it from a hat with several pieces of paper each with a number) prior to testing. Blood samples will be taken, and oxygen consumption will be measured during each session. Each session will be 2.5 hours in length and will be scheduled approximately 7 days apart. See Appendix 1 for a flow chart of the procedures.

## Explanation of Procedures and Risks for All Participants:

Physical Activity Questionnaire (10 minutes):

The purpose of the physical activity questionnaire is to assess your current level of physical activity. This will be completed only during your first session.

2-Day Food Diary (~30 minutes per day):

The purpose of the food diary is to generate a list of foods that you eat 2 days prior to your first session. You will be asked to eat the same type and amount of food prior to each of the sessions, to ensure that your diet does not influence the results of the study. To complete the food diary, you will be asked to record everything you eat and drink for a period of 2 days. You should eat as you would normally and try to eat foods that you would be able to prepare and eat prior to each session. After you have completed the diary, you will be asked to bring it with you to your next scheduled visit.

Blood Draws (about 2 hours 20 minutes):

You will be asked to arrive at our laboratory after an overnight fast (about 8 hours without food or drink except water). We encourage you to drink water in the morning. A catheter will be inserted in your arm, by someone who is certified to draw blood. Rubbing alcohol will be used to clean the surface of the skin and the catheter will then be inserted into the vein in your forearm. Blood samples (each is ~8 mL, which is about 1.5 teaspoons) will be taken for the analysis of several different compounds. The samples will provide us with information about how your metabolism is changing in relation to the supplementation. After the initial blood sample, subsequent blood samples (about 8 mL or 1.5 teaspoons for each sample) will be drawn every 10 minutes up to 1 hour and then every 15 minutes for the following hour, amounting to a total of 11 blood draws over a 2-hour period (total blood drawn: 88 mL). On occasion, **some bruising or discomfort may occur** at the site of insertion. To prevent potential bruising, it is advised that you apply pressure to the site of catheter insertion for 10 minutes directly after blood samples are drawn.

Oxygen Uptake:

We measure the amount of oxygen you take from the air you are breathing by having you breathe through a face mask. The face mask is made of soft rubber that is fitted over the nose and mouth and attached with a netted backing around the head. Attached to the face mask will be a sensor to determine the volume of air that moves into and out of your lungs, and a sample line that takes a small quantity of the air to a gas analyzer system. The facemask and the volume measurement device are sanitized before each person’s use to eliminate any risk of spread of infection. Oxygen uptake will be measured at the start of the study as well as at 30, 60, 90 and 120 minutes.

Supplementation:

At the start of each session, you will be asked to consume gelatine capsules that will be filled with either MSG or a placebo. The dose that you will consume is 150 mg / kg of body weight (~10.5 grams for a 70 kg individual). This is a safe limit of MSG consumption. After 30 minutes, you will be asked to drink either a carbohydrate drink (75g of carbohydrate) or flavoured water. **With MSG ingestion,** **you may experience a burning or tingling sensation, rapid heartbeat, or nausea**. The occurrence of these symptoms is not unusual, and they should subside by 2 hours. At the end of each session, you will receive a beverage and snack. If these symptoms have not subsided before you leave the laboratory, the researchers will provide you with their contact information. If your symptoms have not subsided within 4 to 6 hours after the trial has ended, you are advised to contact the researchers.

Heart Rate Monitor:

Heart rate will be intermittently monitored by an electrocardiograph (ECG) by placing 3 disposable spot electrodes on the skin surface. We will monitor your heart rate at 0, 30, 60, 90, 105 and 120 minutes. The electrodes are normally placed in the lower portion of the chest. This procedure is entirely safe. In a very small group of individuals, **a skin rash might occur** due to the adhesive on the electrodes. There is no way of knowing this ahead of time. The rash, if it develops, will resolve itself within a day or so. However, you are asked to avoid scratching any rash and to keep it clean.

## Exclusion Criteria:

While participation in this study does not pose any high risk to healthy participants, individuals with hypertension, diabetes, and those who experience cardiac arrhythmias will not be included in this study. If you are allergic to rubbing alcohol, then you should not participate in this study.

The participation of individuals with a known intolerance to MSG will be based upon the degree of severity of the intolerance. A health status questionnaire will aid researchers to determine your eligibility. If you are known to experience chest pains and/or cardiac arrhythmias due to MSG ingestion you will be excluded from this study.

## Benefits of Participation:

Participation in this study may or may not be of personal benefit to you. If you are interested in the results of the study or any measurements obtained in the study, we would be happy to provide them upon request. It is hoped that the results of this study will provide information about the role of glutamate in energy and carbohydrate metabolism, which may help aging individuals and patients with diseases like chronic obstructive pulmonary disease. The results of this study will also provide information for future study designs.

## Additional Instructions:

* Participants are asked to refrain from drinking alcohol in the 24-hour period immediately prior to the session as consumption of alcohol will affect the results.

## Current Health Status Form:

This questionnaire asks some questions about your health status and requests some personal information. This information is used to guide us with your entry into the study. We will also be evaluating if you have had any previous adverse reactions to MSG.

## **Participation**:

Your participation in this study is voluntary.

You may withdraw from this study at any time without penalty. To withdraw from the study, indicate this to the researcher or one of the research assistants by saying, "I no longer wish to participate in this study". If you wish to withdraw your study data after participating, please contact the researchers. You can request your data be removed from the study up until ***[insert date]*** as it is not possible to withdraw your data once papers and publications have been submitted to publishers.

## Confidentiality and Security of Data:

Personal health information will be collected during this study. This information may be used by the researchers who are carrying out this study, and will be accessed by only these researchers, as described below.

To ensure the confidentiality of individuals’ data, each participant will be identified by a participant identification code known only to the investigators. Any publications or reports that result from this study will be presented as group data. In the case where individual data is presented, your information will not be identifiable. Your information will be stored in a locked and secure computer. Any identifiable information will be retained for at least ***[insert time period]***, after which it will be destroyed/deleted. While data collected will be retained for at least ***[insert time period]***, after this point, no identifiers will exist linking you to the data collected during this study.

***[If data may be shared in an online repository, please see the ICL guide for details about what information and language to include]****.*

## Participant Feedback:

If you would like to have the results of study, they can be provided to you upon request.

## Remuneration: *[Please see the ICL guide for details and language to include for different types of remuneration e.g., for draws, pro-rating, etc.]*

Your participation in this study is greatly appreciated. At the end of the study, we will provide you with $120 in appreciation for the time you have invested. If you withdraw at any point during the research study, the full amount will be prorated based on the time you have been involved. The amount received it taxable. It is your responsibility to report this amount for income tax purposes.

## Concerns about Your Participation:

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB ***[####] [Replace#### with the file number that is listed at the top of your ethics application]***). If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or reb@uwaterloo.ca.

## Contact Information:

For all other questions, about the study please contact ***[insert Faculty Supervisor/Principal Investigator’s name]***at 519-888-4567 ext. ***[insert ext.]*** or email ***[insert University of Waterloo email]***.

***[Please check that all relevant study details are included, changes are made to the document to accurately describe the study and procedures, and delete the instructional text printed in bold italics before submitting to the Office of Research Ethics for review.]***

**Appendix 1 – Flow Chart of Procedures**

Consent

+ Screening Questionnaire

+ Baecke Questionnaire

2 Day Food Diary Completed & Photocopied

Overnight Fast

Catheter inserted

Baseline Blood Draw, Heart Rate & VO2

MSG / PLB Consumption

Blood draws: 10, 20, 30 min

VO2 & Heart Rate: 30 min

CHO / Water Consumption

Blood draws: 40, 50, 60, 75, 90, 105, 120 min

VO2  & Heart Rate: 60, 90, 120 min

Provide Snack

Repeat for Trials #2,3,4

0

Minutes

10

20

30

40

MSG / PLB

CHO / Water

LEGEND

MSG = monosodium glutamate pills

PLB = placebo pills

CHO = carbohydrate drink

Water = Flavoured Water

 = Blood Sampling

 = VO2 & Heart Rate measures

50

60

75

90

105

120

Trials 1-4 will consist of (in randomized order for each participant):
A) MSG gelatin capsules + Flavoured Water

B) MSG gelatin capsules + Carbohydrate Drink

C) Placebo gelatin capsules + Flavoured Water

D) Placebo gelatin capsules + Carbohydrate Drink