UIW Informed Consent Document

Protocol Title. The Impact of Chocolate on Visual Performance: Psychophysics and Electrophysiology

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2. **Nature:** You have been asked to volunteer as one of 40 subjects in the research project named above.

3. **Purpose**: The purpose of this study is to determine if a single chocolate bar affects your ability and speed to correctly identify black/white and colored targets, affects eye and visual brain-waves, and how well you can see targets off to the side.

4. **Experimental Procedures:** You will be asked to participate in one 1-hour session and two 1.5 hour sessions. In the first session you will undergo baseline testing with the same series of tests you will be given in sessions two and three. In sessions two and three you will be asked to consume a chocolate bar 30 minutes before testing. The chocolate bars contain: cocoa, sugar, soy lecithin, cocoa butter, whole milk powder, cornstarch, palm oil, coloring, salt, cookie crumbs, traces of tree nuts, eggs. If you are allergic to any of these ingredients then you will not be allowed to participate in this study, and by signing the consent form you affirm that you are not aware that you have any allergies to these ingredients. In addition, if you have any history of diabetes or related conditions (high or low blood sugar) you will not be eligible for the study. We ask that you do not consume any caffeinated beverages or supplements on the three days of testing. In order ensure that your unaware of the type of chocolate you consume, we will place an eye patch (like a "pirate's patch) over each eye with a sterile cotton eye pad between the patch and your eyes. We will do this after you are seated and have water handy. You will then be asked to consume the chocolate bar, taking your time and an investigator will be nearby should you need any assistance. We will play music during this time to ensure a relaxed environment. After consuming the chocolate bar, the eye patches will be removed and we will commence testing 30 minutes later. The following vision tests will be administered in each session while you view with your preferred eye:
    a. Visual acuity (smallest letters you can see), small letter contrast sensitivity and large letter contrast sensitivity (low contrast letters which blend into the background. Two measures will be recorded for each test and the first set of measures will be measured with a dark green filter to test your ability to see letters under reduced lighting.
    b. Diopsys® multi-focal electro-retinograms (mfERGs) recorded with skin electrodes which stick to the lower lids. You will view a display with patterns which flash on and off allowing us to record responses from specific sites in your retina, which is the "camera film" of the eye which receives images and sends them to the visual part of the brain at the back of the head. As in all tests, no eye drops will be administered and you only need to view the screen.
    c. Color vision and contrast sensitivity (ability to see low contrast letters) will be measured using a computer-based system which records sensitivity and response times (Innova Systems, Inc.) You will view the display at 4 meters (color vision) and 6 meters (contrast sensitivity) and simply call out the letters you see while the technician records your response.
    d. Konan Medical Cone Contrast Test-HD, a computer-based test which measures red, green and blue color sensitivity will be administered twice to your preferred eye. In this test a colored letter C appears on a display with the gap in the C pointing up, down right or left and you simply indicate which direction the gap is at using a controller.
    e. Your ability to see to the side (peripheral vision) will be measured with a large white board. You will look at an "X" in the center of the board and a black circular target attached to a wand will be moved away from the X until you can no longer see it. This will be performed at 1 meter and 2 meters and repeated twice for your preferred eye. In addition, standard automated field testing (Humphrey FDT

20 deg. threshold test) which simply requires you view with you preferred eye into a device shaped like a microscope and press a button when you see a light off to the side.

f. There is evidence that the increased amount of blue light emitted from contemporary computer, tablet and cell phone displays can contribute to eye fatigue, which is associated with a decreased ability to see high rates of flickering light. But no one knows why the ability to see flicker decreases after blue light and whether it occurs in the retina or the brain. To investigate this, we will record brain and eye-waves from your preferred eye in response to flickering checkerboard and striped patterns (Konan Medical) before and after you view blue and normal displays. Adhesive skin electrodes will be placed on your head to record the brain-waves and a similar adhesive skin electrode will be placed under your preferred eye to record the eye-wave. This will be conducted once followed by 10 minutes of video game play or viewing videos (whichever you prefer) on an iPad Pro adjusted to introduce a strong blue color to the game or video, followed again by the brain and eye waves. This procedure will be repeated but the game or video will be colorized to be warm (yellower, much less blue light) to allow comparison of lighting effects on your eye and brain waves. Different orders (blue vs. warm color) and videos or games will be used in separate sessions.

5. **Discomfort and Risk:** There is no expected discomfort associated with this study. There are no risks involved beyond those experienced during a standard eye exam. No eye drops will be administered and your eyes will not be dilated.

6. **Precautions for Female Subjects:** There are no precautions required for female subjects.

7. **Benefits:** This study offers no direct benefits to you personally, but your participation may help identify benefits of chocolate on visual performance in normal and patients with disease.

8. **Compensation:** You will be given a $25 gift card after completion of the study the entire study.

9. **Confidentiality:** Everything we learn about you in the study will be confidential. If we publish results of the study, you will not be identified in any way.

10. **Stop the Study:** Your decision to take part in the study is voluntary. You are free to choose not to take part in the study or to stop taking part at any time. If you choose not to take part or to stop at any time, it will not affect your current and future status at UIW and RSO.

If you have any questions now, feel free to ask us. If you have additional questions later or wish to report a problem that may be related to the study, please contact the UIW Human Subjects Institutional Review Board (210-805-3036) as needed.

You will be given a copy of this form to keep.

Your signature indicates that you (1) consent to take part in this research study, (2) that you have read and understand the information given above, (3) that you have no know food allergies to the chocolate bar ingredients listed above, and (4) that the information above was explained to you.

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Signature of Participant Date

_____ _____

Signature of Principal Investigator Date