|  |
| --- |
| WATERS COLLEGE OF HEALTH PROFESSIONS |
|  |
| DEPARTMENT OF HEALTH SCIENCES AND KINESIOLOGY |
|  |

**Informed Consent**

**Physiological and Biomechanical Changes during an Ultra-running Event**

You are being invited to participate in the study of the **Physiological and Biomechanical Changes during an Ultra-running event**. The primary investigator is Dr. Li Li who is currently a full research professor at Georgia Southern University. The purpose of this research is to correlate the physiological and biomechanical changes in ultra runners during the 12-, 24-, and 30-hour ultra-running event.

To participate, you must be over 18 years old, have regular physical activity habits, and meet all of the following criteria: be healthy (answered “No” to all the PAR-Q questions, and did not check any boxes in the Present/Past History section of the Health History Questionnaire), and be “recreationally active” (answered “Yes” to the first two questions of the Activity History section of the Health History Questionnaire). You have successfully registered for either 12 hours, 24 hours or 30 hours Bronze Dragonfly Ultra Run Events. You wear smart watch (Apple watch, Garmin watch, Samsung watch, etc.). You agree to take pre- and post- surveys provided by the Biomechanical Lab from Georgia Southern University. After signing the consent document (if you failed to sign it electronically), the data collection is during the ultra-running event events.

We test your gait parameters (i.e. step length, stride width, swing time, etc.) on a walkaway pressure-sensitive mat, 3D running kinematics using a markerless motion capture system during the ultra-running event. We ask you for data collected with your wearable devices (i.e. heart rate, blood pressure, blood oxygen, elevation, step length, cadence) from your smart watch. We analyze your pre- and post-running surveys. Your eligibility will be confirmed by completing PAR-Q and health history questionnaires via email. Once confirmed, you will be instructed to run through the testing site hourly during your ultra-running event. Each testing trial will not interfere your running rhythm. Investigators will instruct and remind the participant before entering the testing zone every hourly.

Pre-running survey will be sent via email for you to take once you signed the electronical consent document. On the event day, you wear your own smart watch to monitor your physiological health parameters. You are expected to share the recorded watch data with investigators within two weeks after the event. You will be guided to enter the testing zone every one hour once the race starts and run over the pressure-sensitive mat. You will be recorded by video cameras for 3D motion analysis usage; however, you will not be informed verbally given the possible disturbance to your running rhythms. We extend an invitation for you to participate in the post-running stretching and relaxation. You will complete the post-event surveys within 2 weeks after the race. You will download your smart watch data and share with investigators via emails within 3 weeks after the race.

The risk of this study includes the possible COVID-19 transmission. However, precautions will be taken with current Georgia Southern policies as well as the Bronze Dragonfly Ultra-run organizers to reduce the spread, including encouraging experimenters and participants wearing masks (except for performing ultra-running events), and having fully vaccinated experimenters. In addition, the risk of the ultra-running event data collection is no greater than risks associated with daily life experiences. Ultra-running eventers who signed up for the events are experienced marathon runners. Participants are fully aware of their health conditions and well-trained for the competition. Researchers will offer guidance of warm-up exercises to minimize the potential running-related discomforts and muscle injuries. To reduce the possible discomforts caused by running, you may perform the post-running relaxation exercise guided by researchers. Your request to stop the procedure will be honored during the test if you feel uncomfortable. You understand that medical care is available in the unlikely event of injury resulting from research. We would contact 911 immediately if any injury were to happen.

You understand that although there is no direct benefit for you to participate in this study, however, the project results can help the community and enhance scientific understanding of the ultra-run. Additionally, more ultra-runners and coaches will benefit from evidence-based strategies that would help improve the performance and reduce the fatigue.

You understand that all personal information and data are only open to the principal and co-investigator. Your privacy is protected confidentially. Your name is deidentified with ID numbers with all collected data. All research-specific data are stored in password-protected computers within lock-protected offices located in Room 1070C, Hollis Building, Georgia Southern University (Dr. Li’s office).

You have the right to ask questions and have those questions answered. If you have questions about this study, please get in touch with the researchers named above, whose contact information is located at the end of this document. For questions concerning your rights as a research participant, contact Georgia Southern University Institutional Review Board at 912-478-5465.

Please understand that your participation is voluntary. You may discontinue your participation at any time. Additionally, the researchers reserve the right to terminate your participation in the study without your consent.

Precautions will be taken in accordance with current Georgia Southern policies to reduce the risk of the spread of communicable diseases (including COVID-19). You have the right to request specific Covid-19 safety measures and we will accommodate as many as possible. We will tell you before you begin participation in any measures we cannot accommodate. Consenting to participate in this research indicates your acknowledgement of the risk of disease transmission. You also acknowledge your requirement to notify the researchers in the event that you test positive for COVID within 5 days prior, are symptomatic prior to or at the time of participation or receive a positive COVID test within 5 days after participation.

If you consent to participate in this research study and the terms above, please sign your name and indicate the date below.

You will be given a copy of this consent form to keep for your records. This project has been reviewed and approved by the GS Institutional Review Board under tracking number H 23272\_\_.

**Title of Project:** **Physiological and Biomechanical Changes during an Ultra-running**

**Principal Investigator:**

 Li Li, PhD.

 Email: lili@georgiasouthern.edu

 Ph: 912-478-0200

**Co-Investigator:**

 Hui Tang, M.S. Student

 Email: ht01253@georgiasouthern.edu

 Ph: 912-582-1607

 Benjamin Paquette, M.S. Student

 Email: bp11854@georgiasouthern.edu

 Petra Kis, M.S. Student

 Email: pk03815@georgiasouthern.edu

 Diego Diaz, M.S. Student

 Email: dc06364@georgiasouthern.edu

 Klylee West, M.S. Student

 Email: kw26744@georgiasouthern.edu

 Katelyn Jackson, M.S Student

 Email: kj11808@georgiasouthern.edu;

 Barry Munkasy, PhD

 Email: bmunkasy@georgiasouthern.edu

If you consent to participate in this research study and to the terms above, please sign your name and indicate the date below:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature Date

**Health History Questionnaire **

Name:

Date of birth:

Date:

Address:

City:

State:

Zip:

Phone (Cell):

(Work):

Email address:

**In case of emergency, whom may we contact?** Name: Phone (Cell):

Relationship: (Home):

Health Care Provider:

Name:

Phone:

Fax:

# Present/Past History

Have you had, or do you presently have any of the following? (Check if yes.)

□ Heart attack

□ Any kind of heart disease or heart surgery

□ Diabetes

□ Prediabetes

□ High blood pressure

□ Low blood pressure □ Kidney disease

□ High Cholesterol

□ Lung disease

□ Seizures

□ Cancer

□ Rheumatic fever

□ Recent operation

□ Other (please describe):

□ Fainting or dizziness

□ Chest pains

□ Palpitations or tachycardia (unusually strong or rapid heartbeat)

□ Known heart murmur

□ Muscle or joint problems (e.g., back, knee)

□ Edema (swelling of ankles)

□ Pain, discomfort in the chest, neck, jaw, arms, or other areas

□ Unusual fatigue or shortness of breath at rest or with light activity

□ Temporary loss of clear vision or speech or short- term numbness or weakness in one side, arm, or leg of your body

□ Shortness of breath while lying down, at night or that comes on suddenly

□ Intermittent claudication (calf cramping)

# Family History

Have any of your first-degree relatives (parent, sibling, or child) experienced the following conditions? (Check if yes.) In addition, please identify at what age the condition occurred.

□ Heart attack

□ Congenital heart disease

□ High blood pressure

□ High cholesterol Explain checked items:

□ Heart surgery

□ Diabetes

□ Other major illness:

# Activity History

1. Why have you decided to seek exercise guidance at this time? (Please be specific.)
2. Were you referred to this program? □ Yes By whom:
3. Have you ever worked with a personal trainer before? □ Yes □ No
4. Date of your last physical examination performed by a physician:
5. Do you participate in a regular exercise program currently? □ Yes □ No If yes, briefly describe:
6. Can you currently walk 2 miles briskly without fatigue? □ Yes □ No
7. Have you ever performed strength training exercises in the past? □ Yes □ No
8. Do you have injuries (bone/muscle disabilities) that may interfere with exercising? □ Yes □ No If yes, briefly describe:
9. Do you smoke? □ Yes □ No

If yes, how much per day and what was your age when you started?

1. What is your body weight now? What was it one year ago? At age 21?
2. How tall are you?
3. Do you follow, or have you recently followed any specific dietary intake plan and, in general, how do you feel about your nutritional habits?
4. List the medications you are presently taking.
5. What are your personal health or fitness goals?