AUBURN UNIVERSITY
College of Education

PARENTAL PERMISSION/CHILD ASSENT
for a Research Study entitled

"*Normative data for balance and postural sway in Southeastern Alabama from ages 5-100 years***"**

(NOTE: DO NOT SIGN THIS DOCUMENT UNLESS AN IRB APPROVAL STAMP WITH CURRENT DATES HAS BEEN APPLIED TO THIS DOCUMENT.)

For children (persons under 18 years of age) participating in this study, the term "you" addresses both the child participants ("you") and the parent of legally authorized representative ("your child").

Your child is invited to participate in a research study to create normative data for balance and postural-sway screening in Southeastern Alabama. Normative data allow us to establish a baseline census distribution, for accurately interpreting postural sway. These data help us to understand how balance develops and changes over the lifespan.

The study is being conducted by *Dr. Harsimran Baweja PT PhD*, Director of Physical Therapy, and the SMaRT Neuroscience Lab in the Auburn University Department of Kinesiology.

Your child is invited to participate because they are 5 to 18 years old, with no known balance deficits, or any medical conditions and injuries that have affected their ability to stand in the previous six months. Since your child is age 18 or younger, we must have your permission to include them in the study.

What will be involved if your child participates?
If you decide to allow them to participate in this research study, we will ask you and your child to visit the School of Kinesiology's SMaRT Neuroscience Lab (Room 136) to: **1)** Provide a written parental permission and a child assent, and fill out a demographic questionnaire (age, gender, race/ethnicity height and weight) (~10 min). **2)** Your child will perform a familiarization session for the tests of standing balance (~2 min). **3)** Perform the Better Balance Test an assessment that measures their balance (~3 min). **4)** Perform Limits of Stability test, to measure their dynamic standing balance (~3 min).

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And finally, **5)** Perform the Clinical Test for Sensory Integration of Balance. This test evaluates the contribution of your child senses - visual, vestibular and proprioception - to their balance (~3 min).

Your child´s total time commitment will be 1 visit of ~30 minutes. Both parent(s) and tester(s) have to be present at all times during the study protocol.

Detailed methods for the research study

- **Step 1: Consent and fill demographic questionnaire.** You and your child will visit the Kinesiology Building room 136 to provide parental permission and a child assent or to decline participation. If you accept, you and your child will fill out a brief demographic questionnaire. Both parent(s) and tester(s) have to be present at all times during the study protocol.
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- **Step 2.** We will provide you and your child with an explanation, demonstration and familiarization with the equipment and protocol.
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- **Step 3.** We will ask your child to stand barefoot with shoulder-width apart and center on the force plate. This is defined as having the medial malleoli (inner ankle bone) of the left and right feet along the horizontal gridline of the plate and feet equal distance from the plate's midline (Figure 1). As a safety precaution throughout the testing session, there will always be at least one staff member standing next to your child.

Figure 1. Representative illustration of test from manufacturer's website with permission.

- **Step 4.** Once your child is properly positioned on the force plate, we will begin the three testing protocols.
- **Step 5.** Perform the **<u>Better Balance Test (BBT)</u>**

The Better Balance test measures your child´s balance.
The test consists of four 20-second trials with a minimal inter-trial of ~10 seconds or as long as needed. Each trial will begin and end with an auditory tone.
Your child will be instructed to stand as still as possible on the force plate with their eyes closed, hand on hips and feet shoulder width apart (Figure 2).
Just prior to testing, we will read the following instruction via an onscreen dialog box:

> This test consists of four, 20 seconds trials. The first trial is a practice trial, and the following three trials are used to measure your balance. For each trial, you will stand as still as possible on the BTrackS Balance Force Plate with your hand on your hips, feet shoulder width apart, and eyes closed. You will hear one tone at the beginning of each trial and another tone when each trial is completed. Do you have any questions?

Figure 2. **Representative illustration of test from manufacturer's website with permission.**

- **Step 6.** Perform **Limits of Stability (LOS) test**

Limits of stability test will be used to measure your child´s dynamic standing balance.

The test consists of one trial of ~3 minutes.

A computer screen displaying the Limits of stability test will be in front of your child, where it can be easily viewed during testing. Your child will be instructed to lean as far as they

can in all directions, while keeping the bottom of their feet completely on the force plate and free of using their arms as they see fit.
Onscreen biofeedback will be given to your child during testing in the form of a yellow dot representing their real-time COP location overlaid on an image of the force plate. As your child´s leans and displace their COP location to a new maximum from the plate's center, additional biofeedback will be given in the form of a blue area over the image of the plate on the screen and a display box will update with the overall real-world size of the created area in cm^2.
For this test, there will be no time constraint, as your child will be instructed to increase the total blue area until they feel it is no longer possible to do so. Once that occurs, the tester will select the "End" button to terminate the test (Figure 3).

Figure 3. Representative illustration of test from manufacturer's website with permission.

- **Step 7.** Perform the **<u>Clinical Test of Sensory Integration and Balance (CTSIB).</u>**

This test evaluates your child´s contribution senses - visual, vestibular and proprioception to their balance.

The test consists of four 20-second trials with a minimal inter-trial of ~10 seconds or as long as needed by your child. Each trial will begin and end with an auditory tone.
They will be instructed to stand as still as possible on the force plate. The first trial (Figure 4A) will be conducted with eyes open while standing on the firm surface of the plate. The second trial (Figure 4B) will be conducted with eyes closed while standing on the firm surface. Trial three (Figure 4C) they will be required to stand on a piece of high-density foam with eyes open. And finally, in trial four (Figure 4D) they will be required to stand on the high-density foam with eyes closed.

Just prior to testing, we will read the following via an onscreen dialog box:

> You are about to perform a Clinical Test of Sensory Integration and Balance or CTSIB. The CTSIB consists of four, 20-second trials that measure your ability to control body sway when sensory feedback is systematically manipulated. For each trial, you will stand as still as possible on the BTrackS Balance Plate with your hands on your hips and feet shoulder width apart. You will hear a tone at the beginning and end of each trial. Your CTSIB results will be based on the Center of Pressure (COP) path length from the forces you place on the BTrackS Balance Plate during standing. Sensory feedback will be manipulated by having you close your eyes or stand on foam in some conditions.

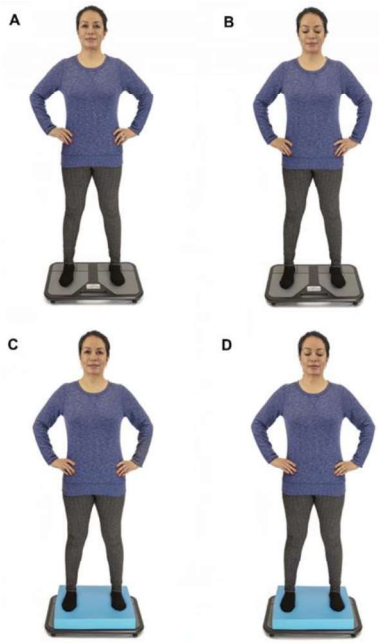

Figure 4. Representative illustration of test from manufacturer's website with permission.

- **Step 8.** Conclusion of the protocol.

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Answers to potential questions

- **Are there any risks or discomforts?** Breach of confidentiality and risk of a ground level fall.
  To minimize the risk of a ground level fall there will always be at least one trained staff member standing next to your child throughout the testing session if they were to lose balance.
  To reduce/eliminate the risk of breach of confidentiality, all participants are assigned a participant ID number. No forms link your child's name to this ID number, and the only form which will contain your child's identifiable information is the parental permission and child assent document. Notwithstanding, we will take extra precautions to ensure forms are protected. First, a single folder will be allocated to contain all participant-signed IRB forms and demographic questionnaire. This folder will be stored in a locked filing cabinet in Dr. Baweja' office in Kinesiology room 221. This is a key-locked office which is also behind a key locked corridor. These two security locked doors will ensure that folders are not accessible to the general public. Likewise, the IRB forms will remain in this office until the 3-year expiratory period. After this period, Dr. Baweja will personally destroy these forms using a double-pane shredder located on the third floor of the Kinesiology Building. Finally, the data that are electronically entered into either Microsoft Excel or statistical software will only be listed as subject numbers. Thus, limiting the ways that these data can be linked to your child. Notwithstanding, we will protect these data by only entering raw data onto computers in laboratory room #136. These computers are password-protected per Auburn University IRB protocols and will be behind a key-card locked door with limited access only to lab personnel and two building administrators (in case someone is locked out of the lab).

  You are responsible for any costs associated with medical treatment for your child.

- **Are there any benefits to your child or others?** Although there may be no direct benefits to your child, the results of this study may benefit others in the future.

- **Will there be any compensation for participating?** You and your child will not receive any compensation for participating in this study.

- **Are there any costs?** If you decide to let your child participate in the study, you will not be monetarily charged for anything.

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- **If you (or your child) change your mind about their participation, they** can be withdrawn from the study at any time. Their participation is completely voluntary. If you choose to withdraw your child, their data can be withdrawn as long as it is identifiable. Your decision about whether or not to allow your child to participate or to stop participating will not jeopardize your or their future relations with Auburn University or the Department of Kinesiology.

- **Your child´s privacy will be protected.** Any information obtained in connection with this study will remain confidential. Information obtained through their participation may be used for publications in professional journals, creating educational materials, presentations in regional, national, and international conferences and professional meetings.

If you (or your child) have questions about this study, please ask them now or contact:

Dr. Harsimran Baweja PT PhD
Director, Physical Therapy
Kinesiology 221
301 Wire Road
Auburn AL 36849

Email: hsb0025@auburn.edu or lab phone: (334) 844-1926.

A copy of this document will be given to you to keep.

If you have questions about your child's rights as a research participant, you may contact the Auburn University Office of Research Compliance or the Institutional Review Board by phone (334)-844-5966 or e-mail at IRBadmin@auburn.edu

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH FOR YOUR CHILD TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO ALLOW THEM TO PARTICIPATE. YOUR CHILD'S SIGNATURE INDICATES THEIR WILLINGNESS TO PARTICIPATE.

_____ _____
Signature of Minor Participant/ Date Investigator obtaining consent/ Date

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_____ _____
Printed Name of Minor Participant Printed Name of Investigator

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Parent/Guardian Signature/ Date

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