INSTRUMENTED STANDING AND WALKING TESTS

1.0 <u>Introduction</u>

Dr. Fay Horak (OHSU) is the recipient of a sub-award from APDM for an NIH funded STTR grant (*A Short, Instrumented Test of Mobility for Neurological Disorders,* 2 R42 HD 071760). The sub-award involves gait and balance data collection for the development of a fall risk evaluation system for clinicians.

The Instrumented Stand and Walk Test (ISAW) is an objective test of mobility that uses inertial sensors worn on the body to quantify many aspects of balance and gait control. In addition, the inertial sensors will be worn by MrOS participants during the 400m walk, to gather more gait-related measurements.

The inertial sensors will only be collected at the OHSU Portland clinic.

1.5 <u>Contact</u>

For questions contact the Balance Disorders Laboratory (Mike Fleming): x6-0842; flemimic@ohsu.edu.

2.0 <u>Equipment</u>

- *Mobility Lab System:* Laptop computer, power supply, 6 sensors with elastic straps, docking station with cord to connect to laptop and another cord for power, access point with cord to connect to laptop, USB remote control, foot-placement template, and Shoe measuring device.
- *USB, Clip-on Audio recorder*
- *Colored Masking Tape*
- *Coban Tape*
- *Tape Measure*
- *Gait Belt*
- *Disposable gloves and Germicidal wipes*
- *Cart to hold all equipment*

2.1   <u>Course Set-up</u>

7m walking course
Place two strips of colored masking tape (24" long) on the hallway floor, 7m apart. The two strips of tape should be placed parallel to each other and in the center of the hallway, so that the subject will not be walking close to a wall. The space should be clear of any other equipment (aside from the Mobility Lab), chairs, etc., so there are no hazards and the subject's performance is not affected by nearby objects.
* DO NOT have subject walk around cones for the ISAW test, as it will affect the way the subject makes a turn.

400m walking course
Please see the 400m Walk protocol for details regarding course set-up.
Obstructions in the exam area that could cause accidents should be removed.

3.0 Participant Preparation

Three different tests (ISAW, ISAW Dual-task, and 400m walk) using the Mobility Lab inertial sensor system will be collected. The ISAW and ISAW Dual-task will take about 1 minute each. In addition, subjects will perform the Dual-task (serial subtraction by threes for 1 minute) while sitting in a chair.

3.1 Exclusion Criteria

Subjects will be excluded if they have dementia that prevents them from following instructions. For the ISAW tests, subjects must be able to complete the test without a walking aid or assistance (note: a subject may use a walking aid or leg brace in daily life, but be able to complete the short ISAW tests without the aid). For the 400-meter walk, a straight cane is allowed; if the subject needs more assistance, then s/he would be excluded.

The vast majority of participants should be able to attempt the ISAW tests. Exclusion from the walking tests will be based on an individualized assessment of impairments and safety concerns. The examiner will describe each test, and then discuss with the subject whether s/he should attempt that test given any physical problems or disabilities present. Refusal or inability to perform a test will be recorded on the data form.

3.2 Participants Safety

For all test items where loss of balance is a possibility you should use the following safety precautions. Place a gait belt around the subject's waist; this can be grabbed if the subject loses balance and needs to be caught. Position yourself standing at the participant's side, slightly behind the person. Your hands should be positioned very close to the participant's trunk/gait belt, but not touching the subject. Be ready to place both hands on the participant/belt to stabilize them if necessary. If the participant loses balance, immediately hold onto the participant with both hands on the belt and trunk and stabilize them. If the participant begins to fall do not try to catch them; hold on the to the gait belt or reach under the participant's shoulders from behind, and slowly ease them down to the floor. This will protect the participant and examiner from injury. Try to maintain a straight back and bend with your knees to lower the person to the ground.

If the participant falls and is not injured, help them up by first having the participant get on their knees or on all fours, place a chair next to the participant, and have the participant support themselves on the chair as you help lift with the gait belt and/or under the shoulders. Do not try to lift the participant from the floor by yourself.

3.3 Footwear

To eliminate the effect of different footwear on test performance, these tests should be performed in tennis shoes or comfortable walking shoes that fit snugly and with minimal or no heels. The subject may perform the ISAW tests with bare feet if appropriate footwear is not available (or with socks, only if socks fit snuggly and walking on a carpeted surface). The clinic may want to purchase a few sizes of inexpensive tennis shoes to have available.

GOOD FOOTWEAR

BAD FOOTWEAR

3.4 Computer Set-Up

The day before a test session, check that the laptop, sensors, and audio recorder are charged. The laptop and docking station need to be plugged into a power source during set-up. After set-up the Mobility Lab system can be moved to testing area and used without being plugged in to a power source.

The Access point plugs into laptop.

Remote has a little thumb drive that slides out of it – that should be plugged into laptop.

Opal sensors should be firmly pushed in docking station plugs.

When everything is set up as above, the lights on the dock should be solid blue. The light on the access point should be solid green. The Opals should take turns blinking green. If everything looks good, now you can *Configure* the system.

Configuring
Click on the Mobility Lab icon to open the Mobility Lab program.

Go into **Settings** tab.

Select Body Sites – Trunk, Lumbar, Wrists, & Feet
 * Check that the correct monitor IDs are entered (ID # on the back of each sensor). If no one else uses your Mobility Lab system, then this information will not change, and you won't have to alter it after the first configuration for the study. If you share the Mobility Lab system with another group, then check at each use to make sure the set-up is correct.

Use Wireless Channel is 90. The channel will only need to be changed if another wireless device in the testing area interfers with the system (*e.g.* EMG or another Mobility Lab). If there appears to be interference, then choice any other channel.

Click *'Apply New Configuration'*.
   You will see a box pop up showing progress as the system configures. Do not touch, jostle or move the equipment during this time or the Opals will not calibrate correctly.

* Next to the 'New Configuration' button you'll also see 'Re-apply Last Configuration.' This will configure the same settings that were selected the last time the system was used. If you know you were the last one to use the Opals, and they aren't being used by anyone else who might've changed the settings, then you can re-apply. Re-applying is faster than doing a new configuration, and the Opals do not have to be in the dock to re-apply; they can be on the subject (*e.g.* if you have an error while collecting data and the

Opals are on the subject, you can choose reapply with the Opals on the person and not have to take them off and put them in dock to reconfigure).

After 1-2 minutes, you should see a '*Configuration complete*' message. Click *OK* and take the sensors out of the docking station. After a few seconds, all sensors should flash green in unison. The access point should also flash green too. Now the Opals are configured and ready to collect data.

*If you've successfully configured and the Opals flash green when you undock them, but it will still be a while until the subject arrives, put them back in the dock so they don't lose charge. As long as you don't change any settings or close Mobility Lab, they'll still flash green and be ready to use when you take them out again.

*After configuration, the laptop and dock do not need to be plugged into power directly, so the cart can easily be moved to the testing area. The only thing that MUST stay connected is the access point to the laptop. If they are disconnected, you have to start over again configuring.

Troubleshooting:
 *Sometimes when configuring you might get a message about a gyroscope in one of the Opals needing to be recalibrated. It means it got moved a little during configuration. Just click *OK* and it will recalibrate, and complete the configuration after that.

*If your configuration doesn't work for any reason, or you get some kind of cryptic error message, just click OK or exit out of the program, unplug and re-plug everything, and try again. That works nine times out of ten.

*If you get a message that says "The following Opals were specified in the configuration: [1, 2, 3, 4] and the following Opals were found docked to your computer: [1, 3, 4]" – then the access point is not recognizing one of the Opals (#2) and you should make sure that it is firmly connected to the dock, not out of charge, has been numbered properly.

Adding a Subject
At the top of the Mobility Lab interface, switch from the **Settings** to the **Studies** tab. Double-click the *MrOS study*.

Now you're in the **Subjects** tab, which lists the subjects in your study. To add a new subject, click the green plus sign 'Add' button down at the bottom of the screen.
Enter this information:

Public ID: Enter the subject's MrOS ID.

Height: Subject's height in centimeters (If needed use calculator function on computer to convert feet/inches to centimeters: Height in inches x 2.54 = Height in cm).

Year of Birth: Put the appropriate four-digit birth year (Just year, not full DOB).

*Height is used for normalization of gait/balance measures and birth year is used to help verify the subject. If you don't have height or birth year info, just leave it blank.

Control? : DO NOT check the *'Is this subject appropriate…'* box.

Click *'Add'* to create the subject. You could also be returning to an existing subject in which case just select them from the list (so you could add a subject(s) before the day of their test session).

Adding Session Information
Click 'Add Session.' A box will pop up asking what kind of session to add. Choose the *MrOS* protocol from the drop down list.

In Notes add: Visit 4 and any other pertinent documentation about the session (*e.g.* 'Subject complains of back pain', 'Subject fell last week', "Difficulty following directions"), then click 'Add'.

Trials tab for the session. Lists the actual trials that you'll collect for your protocol: ISAW, ISAW Dual task, 400m Walk.

Now you're ready to start collecting data. This is the point you want to be at when the subject arrives.

* The subject/session information can be added before configuring, too; it doesn't affect the configuration.

3.5 Placing sensors on subject

Six watched-sized inertial sensors are put on the subject at the chest, waist, left & right wrists, and left & right feet. The sensors are attached using elastic straps.

Place the sensors so that the black side faces out and green light should be at the top (*i.e.,* sensor computer plug down). If green light is toward the bottom, it's upside-down.

The straps should be snug enough that the sensors won't wiggle around on the person, but not so tight as to be uncomfortable.

* The Left and Right sensors are NOT interchangeable – double check that the Opal labeled 'right leg' is on the subject's right foot and the 'left leg' is on the left foot; likewise for the wrists.

Trunk Opal should be positioned right over the rostral part of the sternum.

Lumbar Opal should be positioned below the waist, at the upper pelvis/L4 level.

Occasionally, due to a person's body shape it is difficult to position the lumbar sensor so that it is secure and doesn't wobble when the person walks. In this case, you can wrap Coban tape over the sensor and around the person's torso. Additionally, if the subject has any skin irritation/cuts/excessive sweating at the wrists, then Coban tape can be wrapped around the wrists before putting on the sensors.

3.6 Foot measurement

This measurement can be taken while the person is sitting down. Place the measuring device on the floor and have the subject place their left foot on it with the heel at the back edge. Measure two distances: 1) the foot length (cm) from the ruler and 2) heel to sensor distance – align the small wood piece to the front of the foot sensor and read the measurement.

Record both measurements on #2 of the Data Form.

3.7 <u>Voice Recorder Instructions</u>

The voice recorder used in this protocol is a USB jump drive with a microphone and simple recording mechanism built into it. It captures and stores recordings as .wav audio files, which are contained on the jump drive when you connect it to a computer.

To operate, switch MIC button on recorder from 'OFF' to 'ON'. Light under button will turn RED for several seconds, then BLUE – BLUE means it is recording. When recording is complete, switch back to 'OFF'. The audio files will be stored on the jump drive and labeled REC001, REC002, etc. by default, until you relabel them.
The recorder runs on battery so it should always stay charged. When the battery is getting low, the red/blue light will blink, rather than be solid, during use (it still functions normally, and can get through a few sessions on low battery – but charge as soon as you can after you see blinking). To charge, plug into USB port of any computer that is on and connected to power. Thirty to 60 minutes is sufficient to fully charge. After you retrieve the files from a testing session, it's a good idea to keep the recorder plugged in for a while whether it was blinking or not, just to keep the charge up. We will provide a second voice recorder to keep on hand in case the first fails for any reason – be sure to keep it charged and available also.

It's also a good idea to do an audio test or two before a subject arrives, while setting up the other equipment. Just turn the recorder on, look for the red then blue light, and say 'test' or 'audio test' to make sure it's recording properly.

BEFORE STARTING TRIAL, when subject is in position and needs no further instructions, turn the recorder on and announce in a clear voice the SUBJECT and the TRIAL you are doing; *e.g.,* **"Subject 205, seated trial" "Subject 205, ISAW trial"** Then step behind them and give the command to start in accordance with task instructions. This will avoid any confusion about trial files when you listen to the audio files up on the computer later.

After the trial, turn off the recorder to end recording. Turn on again just before next trial.

If you start a trial but don't finish it for any reason (subject violates instructions mid-trial, distraction in testing area, fire alarm, etc), then before you turn the recorder off, say "this was an aborted trial" or something similar, so you know to discard it when you listen to it later. You can also announce at the beginning of the next trial that it is a second attempt and discard the first.

When starting the Cognitive task, secure USB recorder near the collar of the subject's shirt by taping or clipping recorder to shirt. When a counting trial is ready to begin, switch the MIC button from 'OFF' to 'ON'.

After testing is over, plug recorder into the computer's USB port and find the audio files for the trials. Listen, score the trials (using the subtraction counting sheet), rename the trial files, and save to the Mobility Lab computer. Delete trials from the audio recorder after you know you have a good copy on the computer.

4.0 Detailed Measurement Procedures

4.1 ISAW Test

The ISAW test consists of the subject standing quietly for 30s with their feet positioned in a standardized normal-stance position with their arms at their sides. After 30s, the subject should be instructed to walk for 7 meters, at normal speed, past a line on the floor and then turn around and return to the starting position (walk over the start line).

Double-click on the Trial to open the data acquisition screen.

Start the trial by clicking the '*Record'* button. When you first open the screen, the button will say '*Waiting for sensors to synchronize*…'' and after a few seconds the Record button turns Red. Now it is ready to record data.

* Make sure the 'enable remote' box is checked (at lower left of screen).

Show the subject the *video* example of the ISAW test on the Mobility Lab computer (make sure the computer volume is loud enough). Make sure that the subject understands that test before proceeding (sometimes it takes a couple of tries at the test for the perform it correctly).

Ask the subject if he/she has any questions. If yes, re-explain the procedure briefly.

Lead the subject to the tape on the floor at the beginning of the 7m-walking course. Check that sensors are still correctly positioned, especially the lumbar one.

Once the subject understands the instructions, ask the subject to perform the trial. Have the subject stand at the start line and place the foot template between the person's feet. Have the subject position feet so that the inner edges touch the sides of the template. Then remove the template. During the trial, the tester will be prompted on the computer screen with instructions to tell the subject.

Start the trial by clicking the forward button on the remote control (>) or clicking the Record button with the computer mouse. End the trial the same way – by clicking (>) again on the remote control or a mouse-click.

During the trials stand and walk just behind the subject, staying close but not touching him.

 *For safety of the subject, it is better to use the remote control to start/stop trials, so that you can remain close to the subject.

After the first 30 seconds (timer appears on computer screen when trial begins) of the subject standing quietly, tell the participant to "Walk." The subject will then walk the 7m course at their usual pace, past the line on the floor, turn around and return to the starting location.

End the trial when the person returns to the start line.

Complete #1 & 2 on the Data Form.

4.2 ISAW Dual-task

To determine the impact on mobility of directing attention to a concurrent cognitive task, the second trial of ISAW will be conducted while participants simultaneously performing a serial subtraction task.

Can the subject do the Cognitive Task?

While the subject is sitting in a chair, explain to subject that for the next test, he will need to count backwards by 3's starting from a number that you will give him just before the trial begins. To see if the subject can do the counting task, tell the subject, "I want you to try counting backwards by 3 starting at 100". If he is able to count back by 3's with no problem – great. Proceed to sitting trial. If however the subject in unsure or doesn't know if he can do it, then have him do a practice trial for 30 seconds (not recorded). As he starts counting, encourage him to keep counting out loud and not worry if he makes mistakes; the important thing is to keep counting. Proceed with the actual test if he can do some of the subtractions. Mistakes are OK; we will be quantifying the number of mistakes and the important thing is that the person's attention is distracted from the walking task by doing the counting.

On the other hand, if the person is unable to do any counting backwards by 3's, then enter a 0 on the data form for 'How many numbers counted' and skip the Dual-task ISAW test.

Sitting Subtractions Test

Toggle ON the USB audio-recorder that is attached to the subject's shirt near the collar and say loudly the subject ID# and Trial. Ask the subject to count out loud, backwards by 3's for 60 seconds and that you will tell him when to stop counting. When the subject is prepared, say, "Begin counting backwards beginning with the # 223". Say "Begin" and "End" loud enough to be recorded on the audio recorder. Toggle OFF the audio-recorder after the trial is over.

For the ISAW Dual Task Test

Have the subject stand at the start of the 7m course and position feet with the template. Remove template. Tell the subject, "When I say 'Begin', he/she should start counting backwards by 3. Continue counting while standing for 30sec standing and walking to the line and back just like before. You will continue counting until I say, End".

Ask the participant if they have any questions. If yes, re-explain the procedure briefly.

Say, "Beginning Dual task trial; start counting with the # 410" at the same time as you start the Mobility Lab trial.

End the trial on the Mobility Lab at 60 seconds. Some subjects may finish walking sooner, so have them continue counting while standing until 60 seconds has pasted. Alternatively, a few subjects may still be walking at 60 seconds – just stop the trial without them returning to the start line.

If the subject pauses in counting, remind him to continue counting out-loud.

The sitting and ISAW dual-task tests should be completed regardless of the number of mistakes or how many numbers counted.

Remove the audio recorder from the subject's shirt and turn OFF.

- You will likely need to listen to the audio recording after the test session, to verify how many numbers were counted, and how many errors were made.
- Use the Counting sheet to track responses.

Record scores on #3 and 4 of Data form.

4.3 400 meter Walk

The sensors will also be worn while the subject completes a 400 m walk. Procedures outlined in the 400 m walk should be followed; including wearing shoes and use of a straight cane is allowed, if subject is not comfortable walking without an aid.

Start the 400 m trial on the Mobility lab computer by clicking *'Record'* and tell the subject, "Start walking" and then click *'Stop'* and the the person, "Stop" to end the trial when the subject completes the 400 m.

If at the end of a trial, the recording doesn't stop right away when you click on the Stop button you'll see that the data are buffering from the sensors to the computer (this happens when the sensors are moved far away from the computer; the data is stored temporarily on the sensors and then transferred to the laptop when back in range).

Don't touch any button and wait until the buffering reach 100%. If the participant is far from the Mobility Lab system, sometimes having him/her moving closer to the system will help.

Complete #5 on the Data Form.

5.0 Post Data Collection

5.1 Finishing with sensors

After collecting the final trial of the session, choose *'Keep and Exit'*. This will bring you back to the Trials tab showing your completed trials. If needed, add notes to any trials, sessions, or subject that you want to elaborate on (by clicking the little pencil 'Edit' icon on the bottom panel of the tab).

Clean sensors by wiping off with Germidical wipes (wearing disposable gloves), especially if the sensors touched the subject's skin directly.

After cleaning, re-dock the opals, making sure each one is firmly in the docking station – clicked into the each port and not just resting on it; this is necessary for recharging.

5.2 Data Upload and Transfer

The Mobility Lab data will be uploaded from the laptop to the Balance Disorders Laboratory database (on OHSU secure server). This will be done after the subject(s) leave. The computer needs to have network access (cable is better than wireless). You will click on the *'Upload'* button at the bottom of the Mobility Lab screen to upload all data from the session. From the OHSU server the data will be scrubbed and sent to Coordinating Center.

Complete #6 on Data Form.

5.3 <u>Charging sensors</u>

Plug the dock and computer into a power source and click 'Power off' in the lower left of the screen to power down the opals. When the screen indicates that the power off is completed, lift each sensor out of the dock and after a few seconds the sensors should stop blinking. If the sensors do stop blinking, then push them back into the docking station to recharge.

* If any sensors are still blinking, then the power off did not work, in which case you need to repeat the last step. For instance, if you forget to plug-in the dock to a power supply, the sensors will not power off.

 *If the sensors are left undocked and thus not charging, then the batteries may be run-down and not work when needed for the next data collection.

6.0 Training

- Read and study manual
- Observe administration by experienced examiner
- Practice on volunteers
- Practice data upload procedure with practice data
- Discuss problems and questions with local expert

CERTIFICATION REQUIREMENTS

- Complete training requirements
- Conduct exam on two volunteers while being observed by QC
- Performs exam according to protocol as demonstrated on completed QC checklist

7.0 QA Checklist

- ❑ Explains procedures
- ❑ Properly attachment of sensors
- ❑ Proper set-up and Configuration of Mobility Lab
- ❑ Proper data upload