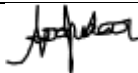
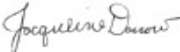
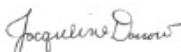
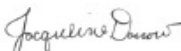


PENS Study
Ten Meter Walk
Standard Operating Procedure
Version 3
17Sep2019



JOHNS HOPKINS
M E D I C I N E

PENS Gait Testing SOP

Action By:	Signature	Date
Dr. Abhay Moghekar Principal Investigator		5/14/2018
Jacqueline Darrow Prepared, SOP Author		5/14/2018
Jacqueline Darrow Prepared, SOP Author		2/5/2018
Jacqueline Darrow Prepared, SOP Author		6/25/2019
Jacqueline Darrow Prepared, SOP Author		9/18/2019

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Document Revision History

Date of Revision	Page(s) Revised	Revision Explanation
5/14/2018	1	Clarified flooring and reduced time for trial to 1 minute
5/14/2018	2	Clarified 3 administrations and use of rolling walker
10/24/2018	All	Rearranged order of sections, added video recording specifications, added video upload and QA
12/18/2018	All	Removed instructions involving use of tripod and changed instructions regarding a single video recording.
5/20/2019	All	Addition of table of contents Addition of optional tripod and site specific IRB approved filming device Added instructions of camera/tripod set up Added the inclusion of audio (if IRB approved)
9/17/2019	6	Added procedure of filming document prior to gait with Subject ID, Event name, and date

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Test preparation/materials required before starting:

- Stopwatch
- Clear pathway, at least 14 meters in length
- Tape measure
- Bright and thick tape (visible from a distance)
- Study provided, password-protected, hard drive encrypted Kindle Fire with a limited user-account (no administrative privileges) – or – IRB approved site specific video device
- Tripod (optional)
- Device Holder with tripod adapter (if using tripod)

Important to note before starting

- Assistive Devices
 - If needed, subjects are able to use assistive devices when doing this task
 - Assistive devices should be **consistent** from test to test.
 - If a subject does use an assistive device, this should be noted on the CRF
 - Subjects should use their customary assistive devices, **NOT** the least assistance possible, to complete test.
 - For subjects with significant gait impairment, the treating neurologist should have the subject use a rolling walker even if this is not the subject's customary device. In general, non-wheeled walkers should not be used
 - The subject cannot lean on the instructor while walking, just the appropriate assistive device.
 - Subject is allowed to touch the wall or arm a maximum of 2 times
 - If subject touches the wall/your arm more than twice, repeat the trial, emphasizing to the subject that he or she is to walk using only the support of an assistive device.

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- If subject does not use an assistive device, notify the study coordinator that the subject may need to be re-evaluated for use of an assistive device.
- If the subject drops their assistive device, restart the trial and record the reason on the source document form.
- Surface: The ideal surface is a hard surface that will be used consistently for all gait assessments (baseline, follow-up, pre and post LP/ELD). A tiled surface is ideal but a hardwood floor would be acceptable. Carpet should be avoided, if possible, if not, the site needs to use the same carpet for future assessments.
- Discontinue further trials if any of the following occur:
 - Subject cannot complete Trial 2 or 3 after a 5 minute rest period
- Subject is not allowed to run. The subject is to walk quickly, but not run
- Shoes
 - The style of shoe needs to be consistent for each subject from visit to visit, it does not matter what kind of shoes are worn
 - Encourage the subject to wear comfortable shoes and discourage subjects from wearing, for example, high-heeled shoes one visit and running shoes the next
- If the subject typically wears an Ankle-Foot Orthosis (AFO) and wears it every time the timed 10-Meter Walk is performed, the subject may wear his/her AFO. Be sure to record this on the CRF
- The subject should walk unencumbered. They should not be carrying any belongings during the timed 10 m walk. Belongings should also not be draped over wheeled walkers

Pathway Setup

Prior to study start, a permanent pathway should be identified and setup. Once setup, the pathway should be used for all gait assessments, alleviating the need to repeat the pathway setup steps for each subject.

1. On the clear pathway, measure 10 m with a tape measure. Ensure an additional 2 m of pathway is available at each end of the finish/start lines.
2. Clearly mark the start and finish lines with tape.
 - a. Make sure the lines are bright and thick so the subject is able to see the tape from the opposite end.
 - b. Replace tape over time as needed.

Camera/Tripod Setup (optional)

1. Set up tripod at one end of the 10M finish line (approximately 3 meters after the tape and slightly off center).
2. Mount the camera on the tripod.
3. Ensure entire pathway is visible through camera.

4. Ensure that the body and feet of the subject will be visible when the subject crosses the finish line.
5. As a privacy precaution, the subject's face should not be visible in the video. If using the tripod and capturing the face is unavoidable, the subject's face should be blurred out. Site will be responsible for blurring faces.
6. If a third party is operating the camera, instruct them not to zoom in and out during the recording.
7. Ensure the Bluetooth and Wi-Fi is turned off.

10 Meter Walk

1. Direct the subject to the start line of the 10m pathway.
2. Ensure audio is on (if IRB approved) and Bluetooth/Wi-Fi turned off.
3. Position the subject behind the starting line tape
 - a. If using a rolling walker, position the feet at the starting line. The walker can be placed ahead of the starting line.
4. Point out and make sure subject knows where the 10 m course ends.
5. Once the subject is in place, reposition yourself at the finish line so you can record the subject walking towards you (unless using tripod).
 - a. If, for safety reasons or if your site SOP is to walk alongside the subject, the tripod will need to be used or another person will be needed to record the assessment.
6. Make sure the stopwatch is set to 0:00.
7. Begin the video recording
 - a. Prior to subject walking, please show piece of paper with the subject ID, Event name, and date.
 - b. Ensure the body and feet of the subject are visible during the entire video.
 - c. Ensure the subjects feet can be seen crossing both the start and finish line.
 - d. Do not zoom in or out during the recording.
8. Instruct the subject to walk 10 m as quickly as possible, but safely.
 - a. Verbal instructions: "I'd like you to walk 10 meters as quickly as possible, but safely. Do not slow down until after you've passed the finish line. Keep your eyes forward, and try not to hold on to the wall (or me). Ready? Go."
9. Start the stopwatch when the lead foot is lifted and crosses the starting line (not when "go" is said).
 - a. If a retrieval is required. Take the subject back to the start line and repeat steps 1-7. See the "Contingencies" below for retrieval reasons.
10. Stop the stopwatch when either foot crosses the finish line, then stop the video recording.
 - a. If using a walker, the finishing time is when either foot crosses the finish line not when the rolling walker crosses the finish line.

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- b. Record the subject's walk time to within 0.1 second, rounding as needed. Round up to the next tenth if hundredth's place is $\geq .05$, round down if hundredth's place is $< .05$.
 - c. Allow the subject to take up to a 5 minute break before starting the next trial. If the subject requires more than 5 minutes, discontinue the assessment and document the information on the CRF.
11. After time is recorded, reset stopwatch.
 12. Position the subject to just behind the line where they are now standing.
 13. Reposition yourself at the finish line and repeat steps 4-11.
 14. Administer the 10 m walk three times

Contingencies

- Record any circumstances that you believe may have affected the subject's performance. These are factors that may have affected the trial but were not severe enough to necessitate repetition of the trial
 - Examples include, but are not limited to, the following:
 - The subject had a cold or reports not feeling well
- If a situation arises that necessitates the repetition of a trial, indicate the reason a trial had to be repeated on the CRF
 - Examples of reasons to repeat a trial include, but are not limited to, the following:
 - The subject tripped or fell during the walk
 - Examiner forgot to start or stop stopwatch
 - Examiner forgot to reset stopwatch in between trials
 - The subject stopped to talk to someone while walking, or another person/thing somehow interfered with walk
 - Record only the times for the three successfully completed trials of the Timed 10-Meter Walk. If the subject could not complete one or more of the trials of the Timed 10-Meter Walk, record this in the appropriate section of the CRF
 - For example, if the subject's disease has progressed and/or physical limitations prohibit him or her from completing the trial, you should indicate "Unable to complete trial due to physical limitations", and record any specifics that you can observe (i.e., subject in a wheelchair now and unable to walk, etc.)
 - If the subject did not complete a trial for any other reason, specify this as well (e.g., subject fell and was too fatigued to complete another trial; subject refused to complete trial)

Video Upload and Quality Assurance:

1. At the end of the day, plug in the Kindle Fire or your site designated device to your password protected work station computer.
2. Copy (or move) each gait video to an encrypted hard drive or network folder.
 - a. Ensure each gait video is named with the subject's OpenClinica ID, an underscore, the assessment timeframe, and the trial number
 - Examples:
 - 1111111_Baseline_1
 - 1111111_4 Month Follow Up_3
 - 1111111_8 Month Follow Up_2
 - 1111111_12 Month Follow Up_1
 - If the assessment is for an unscheduled clinic visit, list the timeframe as "Unscheduled" and provide the date (e.g. 1111111_Unscheduled_03Oct2018_1).
 - b. Upload every trial, including those that had to be repeated. If a trial had to be repeated, add the letter 'r' to the end of the name for the trial that was repeated (e.g. 1111111_Baseline_1r).
3. Delete the gait videos from the Kindle Fire or site designated device.
4. Login into eBinder and navigate to the subject's visit gait folder
5. Upload the applicable video by dragging the file into the "Import Documents" field, or click the "browse" button in the "Import Documents" field.
6. Once uploaded, click the "Manage" drop down button and select "Create Task".
7. Enter the following information:
 - a. Task Title = Gait Review
 - b. Message = Gait Review
 - c. Assign To = Select the name of the reviewer, provided by the Data Coordinating Center.
8. Click "Save". An email notification will be sent to the reviewer.
9. Once the notification is received, the reviewer evaluates the gait video and completes the Gait Adjudication form in OpenClinica.
10. The reviewer sends a PDF copy of the Gait Adjudication form to the blinded assessor and contacts him/her to discuss deviations from the Gait SOP.
11. Repeated deviations from the SOP may result in retraining of site personnel.