PAIN SENSITIVITY

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1. Background and rationale

In MOST, we will assess measures related to pain sensitivity. Individuals experience differing levels of pain for a given injury or degree of inflammation. Changes in pain pathways in response to tissue injury or inflammation can account for such differences. To develop rational approaches to the prevention or management of pain among persons with knee osteoarthritis (OA) requires an understanding of the mechanisms that underlie abnormal pain sensitivity. To date, studies examining the role of abnormal pain sensitivity in OA have been limited to small cross-sectional studies. With the MOST renewal, we will now have the opportunity to assess pain sensitivity in a large cohort of individuals longitudinally.

We will assess pressure pain threshold using a pressure algometer as the primary measure of pain sensitivity. We will assess pressure pain threshold at the knee as a measure of peripheral sensitization, at the tibial tuberosity as an indicator of receptor field enlargement (indicative of central sensitization), and at the wrist (a site remote from the knee which itself is not affected by OA typically), as a measure of an individual's underlying predisposition to pain. We will also assess temporal summation (another measure of central sensitization) using a temporal summation pen at the knee, and evaluate abnormal sensory processing using a number of clinical neurologic assessments.

2. Equipment and supplies

- Two von Frey filaments, strength 2 g ("lower-force") and 26 g ("higher-force")
- Soft brush, width 1 cm (Windsor & Newton Regency Gold 500, size #12)
- Safety pin
- Pressure Algometer (FDIX25)
- Temporal summation pen (60g)
- 2 Small rectangular bean bags (e.g. AliMed Inc, Reorder # 95-506) or a rolled up washcloth (covered by paper towel or table paper)

2.1 Service and maintenance

2.1.1 von Frey filaments

Log date new filaments were first used and mark expiration date (6 months from when received) on filaments. Discard filaments when they are 6 months old and replace with new ones. Visually monitor for bent or broken filaments.

2.1.2 Temporal summation pen

Visually monitor for bent or broken filaments.

2.1.3 Pressure algometer

Contact information: Wagner Instruments P.O. Box 1217, Greenwich, CT, 06836-1217 Tel: 1-800-345-4188; 1-203-698-9681 sales@wagenerinstruments.com

Contact person: Bill Wagner

2.2 Software

None.

2.3 Calibration of pressure algometer

2.3.1 Calibration of pressure algometer against certified weights

The algometer should be calibrated monthly against a balance beam scale using certified weights of 10 and 25 pounds.

At UAB:

The certified weights should be placed on the scale and the scale balanced to assure the scales' calibration for both weights. The scale should then be set at each of the two weights, starting with 5 pounds. One technician should press down onto the scale with the rubber pad of the algometer, keeping the device vertical and with peak hold on. The other technician should watch the balance beam and let the technician with the algometer know when balance is achieved. The reading on the algometer should fall within +/- .5 pounds for the 10 pound weight, and +/- 1 pound for the 25 pound weight. This procedure should be repeated for each of the other two weights and the results recorded on the MOST Algometer Calibration Log.

At U-Iowa:

Follow instructions under UAB, except U-Iowa examiners will use a calibrated balance beam scale, so the first step of calibrating the scale with the certified weights is not necessary. (The balance beam scale must be calibrated annually by a certified Weights and Measures Department and monthly following the instructions for calibrating for linearity under section 2.2 of the MOST "Weight" Operations Manual.)

2.3.2 Examiner monthly algometer calibration

Examiners who are performing pains sensitivity testing must be tested on a monthly basis to insure that they are applying algometer pressure at a consistent rate of 5 kg at 10 seconds +/- 1 second and 7 kg at 14 seconds +/- 1 second. The MOST Algometer Monthly Examiner Calibration Log (located on the MOST website under Study Documents/Certification Forms) must be completed each time examiner calibration is completed.

2.4 Calibration of temporal summation pen

To ensure that the temporal summation pen force is constant throughout the testing protocol, the pen must be calibrated every three months and the results recorded. See MOST Quarterly Temporal Summation Pen Calibration Instructions / Log in Appendix 1. The instructions/log is also posted on the MOST website under "Equipment Calibration."

3. Safety issues and exclusions

3.1 Safety issues

Potential for skin irritation and redness. Small potential for bruising with pressure algometer.

3.2 Exclusions

Testing at the knee

If the participant has had unilateral amputation of the leg above the knee, test the native limb. If both legs have been amputated above the knee, test the wrist only. If the participant has had unilateral or bilateral knee replacements, do not test the patella of the knee on the limb(s) with the replacement; only the tibial tuberosity of the replaced knee will be tested. Areas with open or healing skin wounds will also need to be excluded. Surgical scars over the patella or tibial tuberosity would exclude those particular sites from testing.

Testing at the wrist

Fracture evaluation

If the right wrist has been not been broken in the last 6 months, this wrist is eligible for full testing after further evaluation. If, however, it has been broken in the last 6 months, this wrist is not eligible for pressure pain threshold testing and the left wrist should be evaluated. If the left wrist has not been

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broken in the last 6 months, then this wrist is eligible for full testing after further evaluation. If, however, the left wrist was also broken in the last 6 months, it is also not eligible for pressure pain threshold testing. Whichever wrist from the fracture evaluation is eligible for further evaluation should then be assessed for any other reasons as to why it cannot be tested. If both wrists were broken, then they also must next be evaluated for eligibility for the remaining pain sensitivity tests.

Evaluation of other exclusions for testing at the wrist

Next evaluate the wrists for any other reason they cannot be tested such as presence of cast, other irremovable item covering the skin, regular use of splint/brace, open or healing skin wounds. Surgical scars over the distal radial-ulnar joint would exclude that site from testing. If both wrists are eligible for further evaluation, then first evaluate the right wrist. If the right wrist is ineligible, then evaluate the left wrist. Whichever wrist is eligible will have the pain sensitivity tests performed, and if there were no exclusions due to prior wrist fracture, pressure pain threshold will also be performed. If both wrists are ineligible, then do not perform any of the tests (pressure pain threshold or other pain sensitivity measures) on the upper extremity.

4. Participant preparation

Testing should be performed once the participant has had an opportunity to rest quietly for 2 minutes.

Note that both knees will be tested, and that the distal radial-ulnar joint will serve as a reference site. Please refer to **3.2** for the exclusions to testing of these sites.

Anatomic sites for testing will have been marked previously at a landmarking station. The approximate center of the patella, the tibial tuberosity, and distal radial-ulnar joint will all be identified with a black magic marker. To identify each landmark, please see Anatomic Landmarking operations manual (3B).

4.1 Detailed measurement procedures

4.1.1 Assessment of sensory abnormalities at the knee

Measures of sensory abnormalities at the knee will be assessed in a standardized evaluation of the individual's response to touch, brush movement, and pinprick. Except for pinprick, the stimuli will be applied at a strength that normally does not provoke pain. They may, however, evoke painful responses in the presence of, for example, peripheral or central sensitization.

General instructions

Equipment: At the beginning of each day, place each of the instruments to be used on a small tray table, in order of use (e.g. 2 g, 26 g, temporal summation pen, brush, safety pin, pressure algometer). Use a new safety pin for each participant. Each new safety pin should be cleaned with alcohol before use. Dispose of used safety pins in a sharps container. Make sure that each participant sees the safety pin

being cleaned and being discarded in the sharps container. All items that touch the skin (2 g and 26 g von Frey tips, temporal summation filament tip, algometer tip) must be cleaned with alcohol after use on each participant. The pressure algometer should only be turned on when ready for use. At the end of the day, plug in the algometer to recharge it. If the algometer reads low battery, the device may be used while plugged in.

Participant positioning: The participant should wear shorts and a shirt that allows the wrist to be exposed as pressure from rolled up garments (pant leg or sleeve) will interfere with the testing. Have the participant lie in a supine position on an examining table with the head of the table elevated to about 25 to 30 degrees. The legs should be extended, with one to two pillows as support under the knees as needed. The wrist that is being tested should be comfortably resting on a side table, with palm facing down. The side table's height should be adjusted such that the forearm is resting comfortably on it. Be sure that the side table is at a secure height and won't move down with pressure. The arm being tested should be abducted slightly (no more than 30°). The forearm from the wrist proximally should be supported by a small rectangular beanbag (e.g., AliMed Inc, Reorder # 95-506. Note that a rice bag should <u>not</u> be used since rice can be displaced causing forearm to sink), and a small beanbag or a rolled up washcloth (covered by paper towel or table paper) should be used underneath the palm such that the wrist is flat on the support and the fingers are comfortably positioned. The participant will be asked to have their eyes closed during each testing procedure after first having the demonstration of what the instrument looks like, what you will be doing with it, and for some, what it feels like on the dorsum of their right wrist with their eyes open.

The nature and the purpose of the tests should first be explained to the participant:

Introduction (please read to the participant)

<u>Script</u>: "The next set of tests will help us get a better understanding of what may cause pain in people with knee osteoarthritis. I'm going to be touching your wrists and knees with various devices while your eyes are closed, and will be asking if you experience any pain. We understand that people have different ideas of what pain or discomfort means to them. We want you to think about what pain means to you, and respond to our questions accordingly. Pain is a personal experience. There are no right or wrong answers. We want to know if what you feel is painful to you. If you do experience pain, I will ask you to rate this pain using this scale (optional: show Response Card #27) with which you are already familiar. Zero means no pain and 10 means the worst pain you can imagine."

All tests are performed with the eyes closed. However, the participant will have their eyes open when you are showing them the instrument and showing them what you are going to do with it on your own wrist and/or their wrist. All tests should be applied to the distal radial-ulnar joint of the participant's right hand first as the reference site prior to application to the test sites on the knee. For the wrist, the participant's eyes will remain open so that they can become familiar with the procedure. For the knee, the participant's eyes will be closed.

For each of the neurologic sensory tests (light touch, brush, pin prick): vary the rate between touches. Perform four trials at each site. Do not prompt if there is no response (mark NR). Do not "announce" when you are moving from one site to the next. If all responses are "Now" at a site, simply move to the next site. Otherwise, stop to mark the responses at that site. Complete the rest of the form at the end (i.e., for those that were all "Now" responses). Note that not all neurologic sensory tests will be done throughout the clinic year.

Equipment Two von Frey filaments, strength 2 g ("lower-force") and 26 g ("higher-force") Soft brush, width 1 cm Safety pin Temporal summation pen (60g) Pressure Algometer (FDIX25)

4.1.1.1 Touch

The von Frey filament should be applied a total of four times for the reference test (distal radial-ulnar joint), and the real test: center of the patella and tibial tuberosity. Each application of the filament should be done perpendicular to the skin (i.e., not at an angle) and with enough force to make the filament bend.

Script:

<u>For the wrist:</u> 'I'm going to first use this plastic bristle (show item). This is what I will do with it. (Show how it will be used on your own wrist). This is how it feels." (Touch back of participant's wrist with item.)

"I'm going to start at your wrist and then move to your knees. When asked to rate your pain, please use the 0 to 10 scale. I'll be touching your skin while your eyes are closed. Please say 'now' when you feel this touch your skin, or if you feel pain, say 'pain.' Ready?" (Make sure eyes are closed.)

When switching to the larger filament size start with, "Now I am now going to use a slightly different plastic bristle."

Vary the rate between touches. Do not announce when moving from wrist to knees.

Scoring: Record results on the data collection form:

For both the wrist and the knees, each time the participant says "now" when they felt the bristle, record <u>Now</u> on the data collection form.

If the participant says "pain" when they felt the bristle, record <u>Pain</u> on the data collection form. If the participant did not respond to the stimulus, record <u>NR</u> for "No response" on the data collection form.

Did the participant report pain at least three times? Yes, No

If yes, say:

Script: "Please rate the pain at your [wrist/knee] from this test."

Order of filament portion of the exam is as follows:

Right side

2 g von Frey filament test:

1. reference test on distal radial-ulnar joint

2. center of patella

3. tibial tuberosity

Left side Same order as right side: 1. center of patella

2. tibial tuberosity

<u>Right side</u> <u>26 g von Frey filament test:</u> 1. reference test on distal radial-ulnar joint 2. center of patella 3. tibial tuberosity

Left side

Same order as right side:

1. center of patella

2. tibial tuberosity

4.1.1.2 Temporal summation

Apply the temporal summation pen on the skin four times at the distal radial-ulnar joint, followed by the 30-second test before moving on to the patella (knee cap). The participant's eyes should be closed for this exam. For the trial of four touches, have at least 2 seconds pass between each touch. For both the trial of four touches and the 30-second trials, ensure that the pen slides down the filament only part way (i.e., the neck of the pen should not touch the skin), and do not lift the filament more than 0.5 cm off the skin in between touches to avoid too much force when applying the touches. For the 30-second trials, vary the position slightly along the 'x' marking the site (but do not vary the rate).

<u>Script:</u> "Now I'm going to touch your skin with this pen (show item). You can see that the tip slides back into the barrel (turn pen upside down to show tip retract into barrel) when it touches your skin (push tip onto your own fingertip to demonstrate]. I'm going to start at your wrist, and then test your knees. I'm first going to touch your wrist four times and then ask you to rate <u>any pain</u> you may have had. Please close your eyes. Ready?"

Touch the wrist/knee four times,

After the four repetitions, say: <u>Script:</u> "Please rate <u>any pain you may have had</u> at your [wrist/knee] from this test."

For pain rating scores >0, ask: <u>Script:</u> "Was that painful?" Yes, No, Don't Know

Next, apply the temporal summation pen repetitively on the skin at a rate of once per second (1Hz) for 30 seconds at the site being tested. The participant's eyes should be closed for this exam.

<u>Script:</u> "Now I'm going to touch your skin several times over 30 seconds. When I'm finished, I will ask you to rate the <u>maximal</u> pain you may have experienced during this test. I will also ask you to rate any pain again a few moments after the end of the test."

Start the stopwatch at the beginning of the trial, using it to guide the rate and to time the total trial of 30 seconds. Allow the stopwatch to continue once 30 seconds is over to monitor the 15 second recovery period after the trial is completed (for timing of the final question).

At the conclusion of the trial, ask the participant to rate their maximal pain:

Script: "Please rate the maximal pain you may have experienced at your [wrist/knee] from this test."

For maximal pain rating scores >0, ask: <u>Script:</u> "Was that painful?" Record yes, no, don't know. After 15 seconds post-completion of the trial has passed, say: <u>Script:</u> "Please rate <u>any pain you may be experiencing right now</u> at your [wrist/knee]."

For pain rating scores >0, ask: <u>Script:</u> "Is that painful to you?" Record Yes, No, Don't Know

Repeat the four trials and then the 30-second test as above at the right patella and then the left patella, along with the 15-second post-test pain rating question.

<u>Script:</u> "I'm now going to do the test at your knee, starting by touching your skin four times followed by the 30-second test for each knee."

4.1.1.3 Brush movement

The brush should be moved lightly over the skin, at 3 to 5 cm/sec in a single direction (not back and forth) four times for the reference test (distal radial-ulnar joint), and four times for the real test: at the center of patella and tibial tuberosity.

<u>Script</u>: 'I'm now going to use this brush (show item and demonstrate on your wrist). This is what it'll feel like (touch participant's wrist with item). I'll start at your wrist and then move to your knees. Again, please say 'now' when you feel it, or 'pain' if it was painful. Please close your eyes. Ready?"

Vary the rate between touches. Do not announce when moving from wrist to knees.

Scoring: Record results on the data collection form:

For both the wrist and the knees, each time the participant says "now" when they felt the brush, record <u>Now</u> on the data collection form.

If the participant says "pain" when they felt the brush, record <u>Pain</u> on the data collection form. If the participant did not respond to the stimulus, record <u>NR</u> for "No response" on the data collection form.

Did the participant report pain at least three times? Yes, No

If yes, say:

Script: "Please rate the pain at your [wrist/knee] from this test."

Right side

- 1. reference test on distal radial-ulnar joint
- 2. center of patella
- 3. tibial tuberosity

Left side Same order as right side: 1. center of patella 2. tibial tuberosity

4.1.1.4 Pinprick

The skin should be touched a total of four times for the reference test (distal radial-ulnar joint), and the real test: center of the patella and tibial tuberosity. Only depress the skin slightly with each touch. Use a new safety pin for each participant.

Script:

"I'm now going to gently touch your skin with this safety pin like this (show item and demonstrate on participant's wrist with eyes open). Again, I'll start at your wrist and then move to your knees. As

before, please say 'now' when you feel it, or 'pain' if it was painful. Please close your eyes. Ready?"

Vary the rate between touches. Do not announce when moving from wrist to knees.

Scoring: Record results on the data collection form:

Did the participant report pain at least three times? Yes, No

If yes, say:

Script: "Please rate the pain at your [wrist/knee] from this test."

Discard safety pin in sharps container.

Order of exam is as follows:

Right side

1. test on distal radial-ulnar joint

2. center of patella

3. tibial tuberosity

Left side 1. center of patella 2. tibial tuberosity

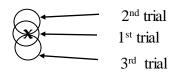
4.2 Pressure – pain threshold

The primary measure of pain sensitivity will be pressure pain threshold. This test will be performed at the distal radial-ulnar joint, the center of the patella, and the tibial tuberosity. (Ensure the arrows point to 'C,' to 'Peak'' (use Scroll/Peak button to set this), and to 'kgf' (use Escape/Units button to set this). Hit 'Select/Zero' button in between readings (after having recorded the reading on the data collection form).

The instrument looks like this:



For each site to be tested, center the rubber tip over the 'x' that is marking the site to be tested for the 1^{st} trial. For the 2^{nd} trial, move the center of the rubber tip superiorly such that the bottom edge of the rubber tip is in the middle of the 1^{st} circle. For the 3^{rd} trial, move the center of the rubber tip inferiorly such that the top edge of the rubber tip is touching the bottom of the 2^{nd} circle and is in the middle of the 1^{st} circle:



For each site being tested, try to ensure that the examiners arms are supported (e.g., both elbows on the examining table) since 'free' arms are more prone to movement and it is more difficult to control the pressure algometer. This may require sitting on a chair, or standing across from the knee being tested. The device should be held with both hands on either side of the device, and thumbs on the top to provide adequate control and pressure.

For all measures, the participant should start by lying supine with their legs extended and right arm (or left arm if right arm can't be tested) resting comfortably on a flat surface of a table, with the elbow at 90 degrees.

<u>Script</u>: "For the last test I'm going to place this device on your wrist and your knees. During this test, pressure will gradually be applied. We are interested in learning the amount of pressure at which you <u>first</u> begin to experience slight pain. As soon as the pressure from the test first produces slight pain, say 'pain.' We are not interested in how long you can tolerate the pain, but rather when the pressure first becomes slightly painful.

"Please tell me your understanding of what will occur during the test and what we'd like you to do."

(Wait for participant's response; reinforce "when pressure FIRST becomes slightly painful" as needed.)

Eyes remain open for this test.

"Ok, I'm going to start at your wrist."

Apply the Pain Test FDIX25 Algometer at each test site: distal radial-ulnar joint, center of the patella, and tibial tuberosity.

Place the tip of the algometer perpendicular to the skin, and apply steady and increasing pressure at a rate of 0.5 kg/sec starting at 0.

(Tell participant before starting each trial so that they are primed to start concentrating as soon as the pressure begins - e.g., "I'm starting the first/second/third test now." After each test: "I'm just going to write that down.")

Record the pressure reading at the point at which the participant reports "pain" on the data collection form and remove the algometer from skin at that point. If 9 kg is reached on the algometer without the participant reporting "now," terminate the trial and record as 9.99 kg.

Repeat each measurement three times at each site.

"I'll now repeat this at your knees."

Threshold levels at each anatomic site will be performed in the same order for each participant. Order of exam is as follows:

<u>Right side exam (participant sitting)</u>: Distal radial-ulnar joint Patella Tibial tuberosity Left side exam (participant sitting): Patella Tibial tuberosity

5. Alert values/Follow-up/Reporting to participants

These test results have no alert values and are not reported to the participant or physician.

6. Quality assurance

6.1 Training and certification

"Master" examiners will train the clinic staff who will be administering the pain sensitivity tests. Clinic staff require no special qualifications or experience to perform this testing. Staff will be initially certified following the below certification requirements. The Pressure Pain Threshold exam will require a second 'master' certification by the 'master' examiner. Staff will be retrained and recertified midway through each examination cycle. The examiner requires no special qualifications or experience to perform this assessment. Training should include:

- Read and study manual
- Attend MOST training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers

- Discuss problems and questions with local expert or QC officer
- Suggestion: Use metronome for training temporal summation and pressure algometry

6.2 Certification requirements

- Complete training requirements
- Pass algometer calibration test (5 kg at 10 seconds +/- 1 second and 7 kg at 14 seconds +/- 1 second)
- Conduct exam on two volunteers:
 - According to protocol, as demonstrated by completed QC checklist

6.3 Quality assurance checklist

Participant positioned properly on examination table

Touch – 2 g von Frey filament

8 .	
	Correct script used to introduce test
	2 g von Frey filament applied four times to wrist
□ Right □ Left □	Participant asked about pain rating if ³ / ₄ were painful at wrist 2 g von Frey filament applied four times to patella
Right 🗆 Left 🗖 Right 🗖 Left 🗖	Participant asked about pain rating if ³ / ₄ were painful at patella 2 g von Frey filament applied four times to tibial tuberosity
Right 🗆 Left 🗆	Participant asked about pain rating if ³ / ₄ were painful at tibial tuberosity

Touch – 26 g von Frey filament

	Correct script used to introduce test
	26 g von Frey filament applied four times to wrist
□ Right □ Left □	Participant asked about pain rating if ³ / ₄ were painful at wrist 26 g von Frey filament applied four times to patella
Right □ Left □ Right □ Left □	Participant asked about pain rating if ³ / ₄ were painful at patella 26 g von Frey filament applied four times to tibial tuberosity
Right 🗌 Left 🗌	Participant asked about pain rating if ³ / ₄ were painful at tibial tuberosity

Temporal Summatio	on – 60g pen - wrist
	Correct script used to introduce test first four trials on wrist
	60g pen applied four times to wrist
	Participant asked to rate pain at wrist
	If rating at wrist greater than 0, participant asked if painful
	Correct script used to introduce 30-second test
	60g pen filament applied on the skin at a rate of once per second for 30 seconds –wrist
	Participant. asked to rate maximal pain at wrist at the end of 30 seconds
	If maximal pain at wrist greater than 0, participant asked if painful
	Participant asked to rate current pain 15-seconds post-test at wrist
	If current pain greater than 0 at wrist, participant asked if painful

Temporal Summation – 60g pen - patella

Right 🗆 Left 🗖	Correct script used to introduce test first four trials on patella
Right 🗆 Left 🗖	60g pen applied four times to patella
Right 🗆 Left 🗖	Participant asked to rate pain at patella
Right 🗆 Left 🗖	If rating at patella greater than 0, participant asked if painful
Right 🗆 Left 🗖	Correct script used to introduce 30-second test
Right 🗆 Left 🗖	60g pen filament applied on the skin at a rate of once per second for 30 seconds – patella
Right 🗌 Left 🔲	Participant. asked to rate maximal pain at patella at the end of 30 seconds
Right 🗆 Left 🗖	If maximal pain at patella greater than 0, participant asked if painful
Right 🗆 Left 🗆	Participant asked to rate current pain 15-seconds post-test at patella
Right 🗆 Left 🗆	If current pain greater than 0 at patella, participant asked if painful

Brush	
	Correct script used to introduce test
	Brush applied four times to wrist
□ Right □ Left □	Participant asked about pain rating if ³ / ₄ were painful at wrist Brush applied four times to patella
Right □ Left □ Right □ Left □	Participant asked about pain rating if ³ / ₄ were painful at patella Brush applied four times to tibial tuberosity
Right 🗌 Left 🗌	Participant asked about pain rating if ³ / ₄ were painful at tibial tuberosity
Pinprick	
	Correct script used to introduce test
	Pinprick applied four times to wrist
	Participant asked to rate pain if painful 3/4 times at wrist
Right 🗌 Left 🗌	Pinprick applied four times to patella
Right 🗆 Left 🗖 Right 🗖 Left 🗖	Participant asked to rate pain if painful ³ / ₄ times at patella Pinprick applied four times to tibial tuberosity
Right 🗌 Left 🗌	Participant asked to rate pain if painful 3/4 times at tibial tuberosity
Pressure pain thres	hold
	Correct script used to introduce test
	Algometer applied to distal radial-ulnar joint until participant reports slight pain (x3)

Right Left Algometer applied to patella until participant reports slight pain (x3)

Right Left Algometer applied to tibial tuberosity until participant reports slight pain (x3)

Reviews form for completeness

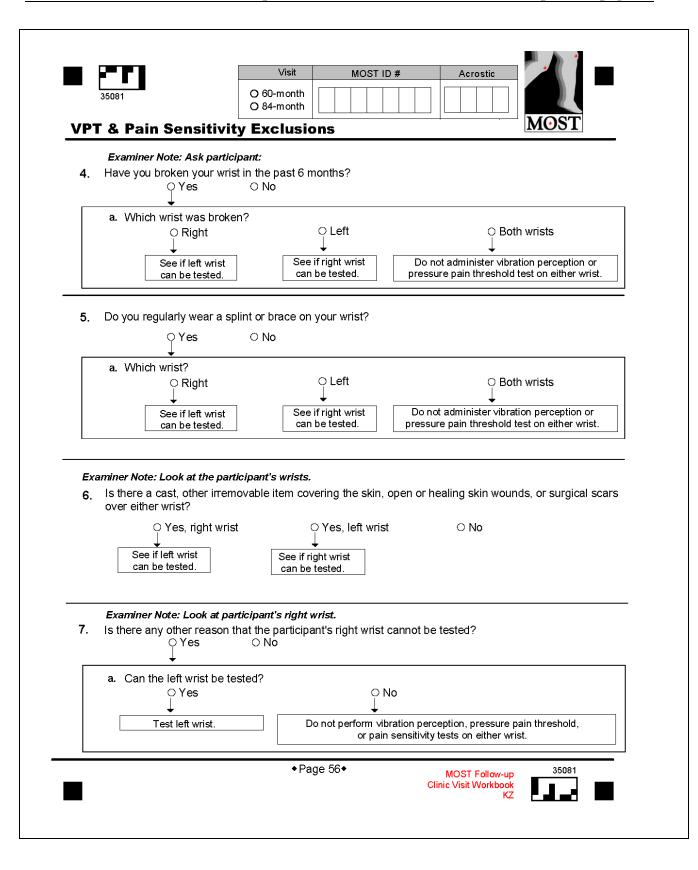
 \Box Correctly completes form

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7. Data collection forms

	50044	Visit O 60-month	MOST ID #		rostic	Staff ID#		
	59041	O 84-month						
VPT	Г & Pain Se	nsitivity E	xclusions				MOST]
.⊦	Have you ever ha							
	• Y ↓	ies ON	No O Don't kno	w/Refu	sed			
a.	Which knee was	s replaced? Right	⊖ Left			0	Both knees	
			↓ Do NOT test L	natella			test R or L pat	
	Do NOT test R	c patella.	Donorieste	patena.		DONOT	lest it of L par	cila.
			ant the following question					
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		/as amputated at Right	oove the knee? O Left			⊖ Botł	legs	
	1	U				Ļ	U	
	↓ 		▼					
		^r exclusions eft leg.	↓ If no other exclusions right leg.	test	lf	no other excl test wrist		
				test	lf			
	niner Note: Look a	eft leg. at the participant's	right leg.			test wrist		
	niner Note: Look a	eft leg. at the participant's	right leg. s legs. unds or surgical scars o			test wrist		
	niner Note: Look a	eft leg. At the participant's healing skin wou	right leg. s legs. unds or surgical scars o			test wrist		
	test I niner Note: Look a Are there open or a. Where?	eft leg. At the participant's healing skin wou Yes O I	right leg. s legs. unds or surgical scars o		atella or t	test wrist	ity?	
	niner Note: Look a	eft leg. At the participant's healing skin wou Yes O I	right leg. s legs. unds or surgical scars o		atella or t	test wrist	ity?	
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		Visit		MOST ID	#	Acro	ostic	Staf	f ID#	•
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31167	O 60-month O 84-month		
Pain Sensitivity	- Touch, 26 g von	Frev filament	MOST
1. DISTAL RADIAL-ULNAR JO	· -	-	◯ Test not done
(Right preferred)	Trial 2	Trial 2	•
Trial 1	ONow OPain ONR	Trial 3 O Now O Pain O NR	Trial 4
a. Did the participant report pair Ask participant:	n at least three times? <i>(Examin</i>	⊥ ner Note: See Trials 1, 2, 3, and	I I 4 above.) ○ Yes ○ No
i. Please rate the pain at your	wrist from this test.		•
00 0		5 06 07 08 09	O 10
2. RIGHT PATELLA	Please say "now" or s	ay "pain."	⊖ Test not done
Trial 1	Trial 2	Trial 3	Trial 4
○ Now ○ Pain ○ NR	ONow OPain ONR	○ Now ○ Pain ○ NR ■ Note: See Trials 1, 2, 3, and	○ Now ○ Pain ○ NR
i. Please rate the pain at your	1 02 03 04 0	5 06 07 08 09	○ 10 ○ Test not done
3. RIGHT TIBIAL TUBEROSIT	-		
Trial 1	Trial 2 ◯ Now ◯ Pain ◯ NR	Trial 3	Trial 4 ○ Now ○ Pain ○ NR
	n actoaoc an oo antoo : (Exami	101 Hole, 000 Huis 1, 2, 0, un	<i>I 4 above.) ♀</i> Yes ○No
Ask participant: i. Please rate the pain at your k 0 0	nee from this test.		
Ask participant: i. Please rate the pain at your k	nee from this test.	5 06 07 08 09	
Ask participant: i. Please rate the pain at your k 0 0	nee from this test.	5 06 07 08 09	0 10
Ask participant: i. Please rate the pain at your k 0 0 0 4. LEFT PATELLA	nee from this test. 1 0 2 0 3 0 4 0 Please say "now" or s	5 0 6 0 7 0 8 0 9 say "pain."	○ 10 ○ Test not done
Ask participant: i. Please rate the pain at your k 0 0 0 4. LEFT PATELLA Trial 1 Now OPain ONR a. Did the participant report pain Ask participant:	nee from this test. 1 0 2 0 3 0 4 0 Please say "now" or s Trial 2 0 Now 0 Pain 0 NR n at least three times? <i>(Examin</i>	5 0 6 0 7 0 8 0 9 say "pain." Trial 3	○ 10 ○ Test not done Trial 4 ○ Now ○ Pain ○ NR
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Ask participant: i. Please rate the pain at your k 0 0 4. LEFT PATELLA Trial 1 Now O Pain O NR a. Did the participant report pair Ask participant: i. Please rate the pain at your k	I O 2 O 3 O 4 O Image: Please say "now" or section of the say "now" or section of the say "now" or section of the say of the sa	5 0 6 0 7 0 8 0 9 say "pain." O Now O Pain O NR <i>ner Note: See Trials 1, 2, 3, and</i>	○ 10 ○ Test not done Trial 4 ○ Now ○ Pain ○ NR 14 above.) ○ Yes ○ No
Ask participant: i. Please rate the pain at your k 0 0 4. LEFT PATELLA Trial 1 Now O Pain O NR a. Did the participant report pair Ask participant: i. Please rate the pain at your k 0 0	Image: Constraint of the sector of the se	5 0 6 0 7 0 8 0 9 say "pain." Trial 3 O Now O Pain O NR mer Note: See Trials 1, 2, 3, and 5 0 6 0 7 0 8 0 9 say "pain." Trial 3	0 10 ○ Test not done Trial 4 ○ Now ○ Pain ○ NR 4 above.) ♀ Yes ○ No ○ 10 ○ Test not done Trial 4
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a. [00	01	02	03	04 (⊃5 (06 (07	08	09	0 1	D	O Test not dor	ne
lf pai	in rating	score	is great	ter than	"0" ask: '	Was tha	at painfu	ul?	i. O	Yes	O No	0	on't know	
30-	sec test	Say t	to parti	<i>cipant</i> : P	lease rat	e the <u>m</u>	aximal (pain vo	ou mav	v ha∨e	experie	nced	at your wrist fror	m this test
b. [00	01	0 2	03 (04 0	5 0	6 O	7 (C 8	09	O 10		⊖ Test not do	ne
lf pai	in rating	score	is grea	ter than	"0" ask: '	Was tha	at painfu	ul? i. () Yes	O No	O Don	't kno	w O Test not	complete
15-se	conds a	fter tes	st S	ay to pa	rticipant	: Please	e rate <u>a</u>	nypair	n you r	naybe	experie	encing	<u>a currently</u> at you	ur wrist.
c. [00	01	02	03	04 ()5 (06	07	08	09	01	0	O Test not do	ne
lf pair	n ratina s	score is	s areate	er than "(0" ask: Is			vou?		Yes	O No	0	on't know	
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ıı pali	n raung				'0" ask: \				-	Yes	O No	-)on't know	
30-se	ec test	Say t	to parti	<i>cipant</i> : P	lease rat	e the <u>m</u>	aximalı	pain yo	ou mav	yha∨e	experie	nced	at your knee fro	m this tes
b.	00	01	02	03 (04 0	5 ()	6 O	7 (C 8	09	0 10		⊖ Test not do	ne
lf pa	in rating	score	is grea	ter than	"0" ask:	Was th	at painfi	ul? i. () Yes	O No	O Don	't kno	w O Test not	complete
n pa				Say to na	rticipant	Diana			n vou r	naybe	experie	encino	currently at you	ır knee.
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Pain Sensiti	vitv . Br	rush						AOST
1. DISTAL RADIAL-UI			av "now" wh	en vou feel '	this brush tou	sh your s		
(Right prefe		say "pain	" if it was pa			JIT your .	C) Test not done
Trial 1 ○ Now ○ Pain		Trial 2	ain ONR	O Now	OPain €	NR	O Now	Trial 4 O Pain O NR
a. Did the participant rep								
Ask participant:			•		· · ·		,	•
i. Please rate the pain at O 0	-	$\bigcirc 2 \bigcirc 3$	04 0	5 06	07 08	09	O 10	
2. RIGHT PATELLA		lease say "no		ain."	T 0		C) Test not done
Trial 1		Trial 2 Now O Pa	ain ONR	O Now	Trial 3 O Pain (NR	O Now	Trial 4 O Pain O NR
a. Did the participant rep	•			-			-	
Ask participant:	•		•		,			<u> </u>
i. Please rate the pain a	-	from this test. $\bigcirc 2 \bigcirc 3$		5 06	07 08	09	0 10	
			0.0				0.10	
3. RIGHT TIBIAL TUBE	ROSITY F	lease say "no	ow" or say "p	ain."			. C) Test not done
Trial 1		Trial 2			Trial 3			Trial 4
O Now O Pain	• J		ain ONR	ONow	O Pain (O Now	
 a. Did the participant reparticipant: 	port pain at le	east three tim	es? (Exami	ner Note: S	iee Trials 1, 2	, 3, and	4 above.)	Yes ⊖No
i. Please rate the pain a	at your knee i	from this test.						
00) 01 (02 03	04 0	5 06	07 08	09	0 10	
4. LEFT PATELLA	F	lease say "no	w" or say "p	ain."			C) Test not done
Trial 1		Trial 2	2		Trial 3			Trial 4
○ Now ○ Pain	ONR O	Now O P	ain ONR	O Now	⊖ Pain () NR	⊖ Now	○ Pain ○ NR
a. Did the participant re	port pain at le	east three tim	es? (Exami	ner Note: S	See Trials 1, 2	, 3, and	4 above.)	Yes O No
Ask participant: i. Please rate the pain a	at vour knee	from this test						+
00		02 03	04 0	5 06	07 08	09	O 10	
5. LEFT TIBIAL TUBE	ROSITY F	lease say "no	ow" or say "p	ain."			C) Test not done
Trial 1	A	Trial 2			Trial 3		<u> </u>	Trial 4
O Now O Pain			ain ONR	ONow	O Pain (O Now	
a. Did the participant rep	oort pain at le	east three tim	es? (Exami	ner Note: S	ee i riais 1, 2	, 3, and	4 above.)	OYes ONo ↓
Ask participant:	t vour knee f	rom this test.				~ •	0.40	
i. Please rate the pain a	-	2 03	04 0	5 06	07 08	09	O 10	

	5 4	O 60-month	MOST ID # Acro	
Pair	n Sensitivity	- Pinprick		MOST
	L RADIAL-ULNAR	JOINT Please say "now" each	h time you feel this pin touch yo	ur skin, or 🔿 Test not done
	(Right preferred) Trial 1	say "pain" if it was pair Trial 2	Trial 3	Trial 4
O Now	O Pain O NR	ONow OPain ONR	O Now O Pain O NR	ONow OPain ONR
		in at least three times? <i>(Examir</i>	aer Note: See Trials 1, 2, 3, an	d 4 above.) ○ Yes ○ No
Ask part i. Please	rate the pain at your O 0		5 06 07 08 0	9 0 10
2. RIGHT	PATELLA	Please say "now" or say "pa	in."	◯ Test not done
	Trial 1	Trial 2	Trial 3	Trial 4
⊖ Now	⊖ Pain ⊖ NR	○ Now ○ Pain ○ NR	○ Now ○ Pain ○ NR	○ Now ○ Pain ○ NR
	participant report pai <i>ticipant:</i>	in at least three times? <i>(Examir</i>	ner Note: See Trials 1, 2, 3, an	d 4 above.) ○Yes ○No
	rate the pain at your	knee from this test.		•
	000	1 02 03 04 0	5 06 07 08 0	9 0 10
3. RIGHT	TIBIAL TUBEROSIT	τγ Please say "now" or say "pa	iin."	○ Test not done
	Trial 1	Trial 2	Trial 3	Trial 4
O Now		ONow OPain ONR	O Now O Pain O NR	
	participant report pa <i>ticipant:</i>	in at least three times? (Examin	ner Note: See Triais 1, 2, 3, an	d 4 above.) ○ Yes ○ No
i. Please	rate the pain at your			0 0 10
	00 0	1 02 03 04 0	5 06 07 08 0	9 0 10
4. LEFT F	ATELLA	Please say "now" or say "pa	in."	○ Test not done
	Trial 1	Trial 2	Trial 3	Trial 4
O Now	O Pain O NR	O Now O Pain O NR	ONow OPain ONR	○ Now ○ Pain ○ NR
	participant report pa <i>ticipant:</i>	in at least three times? <i>(Exami</i> i	ner Note: See Trials 1, 2, 3, an	d 4 above.) ○ Yes ○ No
-	rate the pain at your	knee from this test.		
	00 0	1 02 03 04 0	5 06 07 08 0	9 0 10
5		γ Please say "now" or say "pa	ain "	⊖ Test not done
D. LEFT	Trial 1	Trial 2	Trial 3	Trial 4
O Now	O Pain O NR	O Now O Pain O NR		
a. Did the		in at least three times? <i>(Examir</i>	ner Note: See Trials 1, 2, 3, an	
Ask par	ticipant:			•
I. Please	rate the pain at your 000	r knee from this test. 1 02 03 04 0	5 06 07 08 0	9 0 10
		A Dawa C	4◆ MOST Fol	4454
_		◆Page 6-	Clinic Visit Wo	

 Distal radial-ulnar joint, right preferred 	◯	◯ · kg ⊖ Test not done	○ Test not done	
SUPINE - LEGS 2. Right patella	Trial 1	Trial 2	Trial 3	
3 . Right tibial tuberosity	◯ · ◯ kg ○ Test not done	◯ · ◯ kg ⊖ Test not done	◯ • ◯ kg ⊖ Test not done	
4. Left patella	◯ · kg ○ Test not done	◯ · kg ○ Test not done	O Test not done	
5. Left tibial tuberosity	◯ · kg ○ Test not done	◯ · kg ○ Test not done	O Test not done	

Appendix 1 MOST Quarterly Temporal Summation Pen Calibration Instructions / Log

MOST QUARTERLY TEMPORAL SUMMATION PEN CALIBRATION INSTRUCTIONS / LOG	
Instructions:	
Clinical Center: O Alabama O Iowa	
To ensure the pen force is constant throughout the testing protocol, measure the force output from the pen stylus using a gram scale (digital or analog) every 3 months:	
Task 1: Before measuring the pen force output, calibrate the gram scale using certified weight(s) according to the manufacturer's specifications.	
Task 2: Zero the scale initially if necessary.	
Task 3: Hold the canister vertically over the scale and apply the pen filament/stylus to the scale. Slide the canister down the filament until approximately only 1 cm of filament is visible to ensure the mass is no longer supported by the canister, but the canister is not touching the scale surface.	
Task 4: Hold this position for approximately 2 seconds to achieve a steady-state gram measure to within 0.1 g.	
Task 5: Remove the filament/stylus from the scale, and ensure the scale returns to zero. Re-zero if necessary.	
Task 6: Repeat the measurement process (Tasks 2-5) 2 times for a total of 3 measurements	
Task 7: All measurements should be within 1 g of 60 g and 1 g of each other; if not, repeat Tasks 2-5 up to 3 times until 3 consecutive measurements are within the specified criteria. If 3 consecutive measurements are not within the specified criteria, go to Task 8.	
Task 8: Record the 3 measurements and the highest value of the 3 measurements (achieving repeatability within 1 g of each other).	
Task 9: If values are not within 1 g of 60 g and 1 g of each other, 1) check the filament for any visible damage that may alter the force readings, 2) remove the mass and weigh separately to ensure the mass has not been altered and 3) notify the clinic QC Officer who will notify Lars Arendt-Nielsen at the Center for Sensory-Motor Interaction. Do NOT continue to use this pen device for further testing until it can be correctly calibrated or replaced.	
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MOST Quarterly Temporal Summation Pen Calibration Log						
Date Examiner Staff ID#	Measurement #1	Measurement #2	Measurement #3	Highest Val of 3 Measureme		
		-				
* If 3 measurements are not	t within 1 g of 60	g and 1 g of each o	other, notify clinic	QC Officer.		