

### **SUBJECT RECRUITMENT PROCEDURES:**

Identify potential patients with low back pain (LBP). These will only be patients who are referred to Physical Therapy for LBP. Do not “cold-call” previous patients to participate in this study or invite individuals who may call about the possibility of participating. Sometimes word gets out that a study is ongoing and that people are getting paid, and before you know, everyone has LBP. Only take referrals from physicians. Describe the study to the patient and invite them to participate.

### **INFORMED CONSENT:**

Have subjects read and sign the Informed Consent document. All subjects must complete the Informed Consent document prior to any screening examination or data collection procedures can begin. Any of the participating therapists may consent a patient to participate; however, no other individuals may consent a patient into the study. Ensure the patient initializes all pages of each of the two copies of the Informed Consent document (except for the last page where their signature will be present). Both copies should then be signed by one of the participating therapists in the “Investigator’s Signature” block and by another clinic staff member in the “Witness Signature” block (if applicable on your form). Do not have a friend or family member of the subject sign in the “Witness Signature” block. Hand one copy of the Informed Consent document to the subject for them to keep and place the other copy of the Informed Consent document in the unmasked folder in a secure location that is separate from the masked study folder which contains the majority of the subject’s data collection records. Patients are considered enrolled into the study once they sign this statement.

### **SCREENING EXAMINATION PACKET FOR INCLUSION/EXCLUSION CRITERIA:**

In order to screen subjects according to the inclusion/exclusion criteria, have the subject complete a screening examination packet of questionnaires. You will have multiple copies of these packages that are not initially included in the subject’s masked study folders. Be sure to keep a master copy somewhere so that you can make additional copies if necessary. These packets are stapled in order to keep them in some semblance of order, but you will need to remove the staple to distribute the information to the appropriate folder. Be sure to keep track of subjects that you screen but who do not meet the eligibility criteria (i.e. ODQ < 30, + neuro signs, etc.) on the “Tally Sheet for Subject Ineligibility/Refusal” tracking form provided. It is designed so all that is need to place a tick mark next to the pertinent inclusion/exclusion criteria. The screening examination packet includes the following forms:

**NOTE:** Once the patient completes the Informed Consent document, the screening examination is completed, and the baseline physical examination is completed, you will then place the forms in the appropriate location (subject’s individual masked folder or the unmasked folder).

1. 2 copies of the Informed Consent document (Place one copy of this form in the unmasked folder that contains the Subject ID-Name Link form and the Subject Payment form.)
2. Subject ID-Name Link form (Place this form in the unmasked folder that contains the Informed Consent document and the Subject Payment form.)
3. Pain Diagram and Rating form\*\*\* (Place this form in the subject’s masked folder.)
4. Oswestry Disability Questionnaire form\*\*\* (Place this form in the subject’s masked folder.)
5. Functional Rating Index (Place this form in the subject’s masked folder.)
6. Fear-Avoidance Beliefs Questionnaire (Place this form in the subject’s masked folder.)
7. Demographic Information form\*\*\* (Place this form in the subject’s masked folder.)
8. Screening Examination form\*\*\* (Place this form in the subject’s masked folder.)
9. Physical Examination form\*\*\* (Place this form in the subject’s masked study folder when the physical examination is completed.)
10. Subject Payment form (**NOTE: Do not complete the payment amount or the payment schedule until the**

**subject's participation in the study is over. Only fax this form to me once at the completion of the subject's participation. After faxing me a copy, place this form in the unmasked folder with the Informed Consent document, and Subject ID-Name Link form.)**

If you want to facilitate the process, subjects must at a minimum complete the information that has 3 asterisks next to it in order to complete the screening examination. This includes the following:

1. Pain Diagram and Rating form
2. Oswestry Disability Questionnaire form
3. Demographic Information form (Parts a.[Demographics] and b. [Health History])
4. Part II. Neurological Screening, p. 3 of the Physical Examination form (Only need to complete this at this stage if you suspect signs consistent with nerve root compression and need to rule it out. Otherwise, you will pick it up during the baseline physical examination.)

At a minimum, therapists must also complete the Screening Examination form to determine the subject's eligibility status. **However, the remainder of the forms must still be completed if the subject is deemed eligible, so it probably makes sense to have the subject complete all the forms in the screening examination packet (except for the Physical Examination form) at one sitting. You will have a good idea if they are eligible as soon as they complete the Oswestry Disability Questionnaire form and if you don't suspect any signs of nerve root compression.** If you suspect the subject may have signs of nerve root compression, you may have to do a quick screening examination to examine the exclusion criteria relevant to nerve root compression. **If the patient consents to participate and is deemed eligible to participate, place the forms from the screening examination packet into the appropriate folder (masked vs. unmasked).**

#### **Screening Examination form:**

The inclusion/exclusion criteria for the study are listed on the Screening Examination form. The method by which to determine whether the subject meets these criteria is enclosed in parentheses on the form. In order to establish whether the subject has an Oswestry score of at least 30 points, use the procedure below to score the Oswestry.

#### **Scoring the Oswestry**

- a. Assign a score to each section. Each section can be scored from 0-5, based on the selection chosen by the subject. If the subject marks the first response, assign a score of 0, the next response a 1, the next response a 2, and so on, with the final response being assigned a score of 5. Below is an example of the section called "Pain Intensity" with the corresponding score that should be assigned if that response is selected.

#### **Pain Intensity**

- I can tolerate the pain I have without having to use pain medication. **(0)**
- The pain is bad but I can manage without having to take pain medication. **(1)**
- Pain medication provides me complete relief from pain. **(2)**
- Pain medication provides me with moderate relief from pain. **(3)**
- Pain medication provides me with little relief from pain. **(4)**
- Pain medication has no affect on my pain. **(5)**

- b. Add up the individual scores for each section.

- c. Divide this result by 50, and report as a percentage (ex.  $30/50 = 60\%$ ). In the event a subject does not complete each section adjust the denominator accordingly. For example, if the subject does not answer the question with respect to "Social Life", divide by 45 instead of 50. Divide by 40 if they leave 2 sections blank, 35 if they leave 3

sections blank, and so on. **(Note: Therapists should always check to ensure all items are completed to minimize having to adjust the score.)**

- d. Mark the score on the form and circle it.

## COMPLETION OF FORMS

Be sure that subjects and therapists complete every form and all items of every form. It is easy to skip over questions and components of the examination, and some of these items may be key pieces of information necessary to properly analyze the data. I would recommend that you verify the completeness of every form as subjects hand them back to you and after therapists complete any forms. By doing this, if an item is missing, you can immediately have them complete the item, rather than having them recall the information several days after the form was completed.

## BASELINE PHYSICAL EXAMINATION

Have subjects complete any remaining forms (in the screening examination package and/or in their study folder) for the Baseline Examination that may not have been necessary to complete the screening examination. The following forms may not have been initially completed in full:

1. Functional Rating Index (if not completed during the screening examination)
2. Fear-Avoidance Beliefs Questionnaire (if not completed during the screening examination)
3. Demographic Information form (if not fully completed during the screening examination)
  - a. Demographics
  - b. Health History
  - c. Employment Background
  - d. Treatment Expectation
4. Subject ID-Name Link form (Place this form in the unmasked folder that contains the Informed Consent document and the Subject Payment form.)
5. Subject Payment form **(NOTE: Do not complete the payment amount or the payment schedule until the subject's participation in the study is over. Only fax this form to me once at the completion of the subject's participation. After faxing me a copy, place this form in the unmasked folder with the Informed Consent document, and Subject ID-Name Link form.)**
6. Physical Examination form (This will almost certainly not have been completed during the screening examination. Place this form in the subject's masked study folder when the physical examination is completed.)

Conduct the baseline physical examination. **See the guide beginning on the next page to ensure therapists are using the correct operation definitions in the performance and interpretation of examination findings.**

## Guide to the Physical Examination

**Date of onset:** The subject has already recorded this once on p. 1 of the Demographic Information form; however, please ask this question again to confirm the subject gives you the same answer. The date of onset should be with respect to the most recent episode for which they are currently presenting, not the date at which they first ever had an episode of back pain. The answer to this question is important as it will be used to assess the duration of symptom criteria for success.

### I. Historical Information

#### 1. Mode of Onset:

Four options are available, only one may be chosen:

1. Gradual - Patient is unable to identify a discrete moment when LBP began.
2. Sudden (Minimal/No Perturbation) - LBP began at a discrete moment in time, but was not associated with any abnormal movements or trauma, or was associated with an routine activity that involves very low stresses (e.g. picking up a light object from the floor)
3. Missed-Step - LBP began following an awkward step or stride (e.g., missing a step on a flight of stairs), but does not involve an actual fall to the ground.
4. Traumatic - LBP began at a discrete moment, and was associated with an event or activity involving moderate or high stress on the spine.

Chose the most appropriate option describing the circumstances surrounding the onset, or select other and explain.

#### 2. Distribution of Symptoms:

This information should be gathered from the pain diagram and confirmed by asking the patient if the diagram accurately reflects the symptoms that he or she experiences. Each of the five anatomical areas should be specified with the appropriate symptom distribution or marked as "No Symptoms". The options for the type of symptoms, location, and nature are mutually exclusive, thus only one option may be selected for each area.

1. Lumbar spine is defined as the area at or above the lumbosacral junction. Central symptoms occur at or very near the spinal column. Bilateral symptoms occur to both sides, but occur outwards from the spinal column. Right or left refer to symptoms occurring out from the spinal column on one side only.
2. Buttock refers to the area below the lumbosacral junction and above the gluteal fold. Central symptoms occur along or very near the sacrum spinal processes. Bilateral symptoms occur to both sides, but occur outwards from the sacral spinous processes. This would include the region of the PSIS and sacral sulcus. Right or left refer to symptoms occurring out from the sacral spinous processes, including the regions of the PSIS and sacral sulcus, but on one side only.
3. Groin refers to the inguinal region of the proximal anterior thigh.
4. Thigh is the area below the gluteal fold and above the popliteal fold of the knee on the posterior aspect of the leg.

5. Lower leg/foot is the area below the popliteal fold of the knee.

The nature of the symptoms in each of the anatomical areas is described in one of three ways, only one option may be chosen for each anatomical region:

- Constant - Always present with no variation in intensity
- Intermittent - Present at times, completely absent at other times
- Variable - Always present, but intensity varies

### **3. Ordering of Symptoms:**

The patient is asked to identify which posture (sitting, standing, and walking) is the worst and best with regards to symptoms, or if there is no difference in the three postures (indeterminate). More than one posture may be selected for each category (best and worst); however, the same posture should not be checked for both categories. A posture may only be identified for one of the categories, with the other left blank (e.g. sitting is clearly the worst, and no posture is identified as best).

### **4. Temporal Ordering of Symptoms:**

The patient is asked to identify which time of day (morning, midday, evening, and night) is the worst and best with regards to symptoms, or if there is no difference in their symptoms based on the time of day (indeterminate). More than one time of day may be selected for each category (best and worst); however, the same time of day should not be checked for both categories. A time of day may only be identified for one of the categories, with the other left blank (e.g. morning is clearly the worst, and no time of day is identified as best).

### **5. Prior History of LBP:**

- a. The patient is asked about prior episodes of LBP that have caused him to miss work or reduce his functional activity level. If the answer is no, the subsequent questions are not answered.
- b. The number of prior episodes is established into one of the four categories listed.
- c. The frequency of prior episodes is established into one of the three categories listed.
- d. The location of symptoms of previous episodes is established. If any of the prior episodes involved leg pain, this option is marked. Both options may be marked.
- e. The events leading up to prior episodes are determined; more than one option may be selected if the patient has had multiple prior episodes.
- f. The patient is questioned regarding any treatments attempted for previous episodes. If a treatment has been used, the response to the treatment is ascertained.

## **II. Neurological Screening**

### **1. Sensory Examination:**

Sensory examination is carried out with pin prick examination in the specified anatomic areas bilaterally, while the patient has his eyes closed. The patient is asked if the sharp sensation is of equal intensity on both sides (WNL), or if one side feels more dull than the other (Diminished), or if one side is unable to be felt (Absent).

## **2. Motor Examination:**

Manual muscle testing is performed bilaterally. Grading is either WNL (equal bilaterally) or diminished (less strength than the other side). Each movement is also assessed as painful or not painful during testing. All testing is performed with the patient seated:

- Hip flexion - the hip is flexed to near end range and pressure is applied to the anterior thigh into hip extension.
- Knee extension - The knee is placed in a position slightly less than full extension. One hand stabilizes the patient's thigh, while the other applies pressure on the anterior tibia into knee flexion.
- Dorsiflexion - The foot is placed in full dorsiflexion with some inversion. One hand stabilizes the distal tibia, while the other hand applies pressure on the dorsum of the foot into plantar flexion with some eversion.
- Hallux Extension - With the shoes off, the great toe is placed in extension. One hand stabilizes the foot, while the other hand applies pressure on the dorsum of the distal phalanx of the great toe into flexion.
- Ankle Eversion - The foot is placed in full eversion and dorsiflexion. One hand stabilizes the distal tibia, while the other applies pressure on the lateral aspect of the foot into plantar flexion and inversion.

## **3. Deep Tendon Reflexes:**

Reflexes of the lower extremity are tested bilaterally with the patient seated. The quadriceps reflex is tested by tapping the patellar tendon and observing for knee extension. The ankle (Achilles) reflex is tested by grasping the patient's foot and placing it into slight dorsiflexion. The Achilles tendon is tapped and the examiner observes and feels for ankle plantar flexion. Reflexes are graded as "WNL" when equal to the other side, "Diminished" if a response is of reduced vigor as compared to the other side, or "Absent" if no response is elicited.

## **4. Tension Signs**

1. Straight Leg Raise is performed with the patient supine and the head relaxed and both hips and knees extended. The examiner grasps under the ankle on the side to be tested and passively lifts the leg. The leg should remain straight and in neutral hip rotation. The leg is lifted until the patient reports that pain is produced. A test is considered positive when raising the leg less than 45° reproduces sciatic pain.
2. Femoral Nerve Stretch is performed with the patient prone. The examiner passively flexes the patient's knee and notes any report of pain from the patient. The test is considered positive if femoral nerve pain is reproduced. This is determined by evaluating the location and nature of the pain produced during the test movement. If the anterior thigh symptoms are reproduced, the test is judged to be positive. However, if pain is reproduced only in the back, the test is judged to be negative.

## **III. Standing Examination**

### **1. Postural Observation:**

The posture is observed. Postural deformities should be considered as postural adaptations to injury or pain, not normal variants of posture frequently observed in both healthy and symptomatic individuals (e.g. reduced or accentuated lumbar lordosis). Three options are possible. Both an acute Kyphosis and a lateral shift may be present in the same individual:

1. WNL – This should be the selection if and acute kyphosis and a lateral shift are not present. In other words, if you are having to debate about the presence of an acute kyphosis or a lateral shift, mark it as WNL.
2. Acute Kyphosis - A frontal plane deformity in which the patient adopts a flexed posture due to injury or pain.
3. Lateral Shift - A sagittal plane deformity in which the shoulders are notably displaced to the left or right in the frontal plane with reference to the pelvis. The direction of the lateral shift is determined by the direction of the shoulders relative to the pelvis.

## **2. Pelvic Landmarks:**

The bony landmarks of the pelvis are palpated, including the posterior superior iliac spine (PSIS), and iliac crest which are palpated from behind the patient, and the anterior superior iliac spine (ASIS), which is palpated facing the patient. For each landmark, palpation is performed bilaterally, and a judgment is made:

1. High Right - The right landmark is higher than the left landmark.
2. High Left - The left landmark is higher than the right landmark.
3. Level - No difference in height is found between the two landmarks.

## **3. Single Movement Testing and Status Change with Trunk Movements:**

Active range of motion is tested with the patient standing. Single movement testing is performed. **The patient is first asked about his symptoms while standing, prior to any movement testing!** The patient is instructed that these symptoms will serve as a baseline level, and it is the change in symptom location and/or intensity that should be reported. The range of motion values are measured in the following manner:

### **Single Movement Testing:**

- Total Flexion - The center of the inclinometer is centered over the spinous process of T<sub>12</sub>. The inclinometer is zeroed. The patient is instructed to bend forwards as far as possible without bending the knees.
- Pelvic Flexion - The measurement of flexion is repeated with the center of the inclinometer placed over the S<sub>2</sub> spinous process, which can be palpated between the PSISs. This measurement represents pelvic flexion.
- Extension - The center of the inclinometer is centered over the T<sub>12</sub> spinous process. The inclinometer is zeroed. The patient is instructed to bend backwards as far as possible without bending the knees.
- Left and Right Sidebending - The spinous process of T<sub>12</sub> is identified. The center of the inclinometer is placed just above this point parallel to the axis of the spinal column, and is zeroed. To measure right sidebending, the inclinometer is placed on the left side and to measure left sidebending, the inclinometer is placed on the right side. The patient is instructed to bend to the right or left as far as possible with the fingertips reaching as far down the side of the thigh.
- Lumbar Flexion - Lumbar flexion is calculated by subtracting the pelvic flexion from the total flexion. (Note: Therapists don't have to calculate this as I can get this from the total and pelvic flexion values recorded.)

### **Status Change with Trunk Movements:**

With each movement performed, the examiner makes a judgment as to whether the patient's symptoms are improved or worsened after each movement. Therapists should also record whether the improvement or worsening

in status is due to changes in pain (“My pain is worse.” or “Now my pain is less.”) or changes in the location of the symptoms (“My symptoms have moved up my leg closer to my back” or “My symptoms have moved closer to my foot.”). Centralization of symptoms should indicate an improvement in status, and peripheralization of symptoms with movement should indicate a worsening in status. Only one term (“Improve” or “Worsen”) can be used with each movement tested. However, it is possible that with extension, for example, the patient’s symptoms may centralize (i.e. improvement in status), but the patient may describe their pain as getting worse. If this is the case, alterations in paresthesias take precedence over alterations in pain, thus this patient would be judged to have improved with this movement, and the improvement would be marked as occurring because of centralization. Improvement and worsening in status are defined below:

1. Worsen -

- a. Symptoms present (or produced) increase in intensity with the test movement. When the neutral position is resumed the intensity remains higher than baseline for at least 30 seconds after completion of the movement.
- b. Or, a paresthesia is produced which was not present prior to the movement,
- c. Or, a pain or paresthesia moves distally away from the spine

2. Improve -

- a. Symptoms present are diminished or abolished during the movement. When the neutral position is resumed, the symptoms remain decreased in intensity for at least 30 seconds.
- b. Or, a paresthesia present at rest is abolished.
- c. Or, a pain or paresthesia moves centrally towards the spine.

3. Status Quo (ISQ) -

- a. Test movement does not cause improving or worsening of symptoms

**4. Standing Flexion Test:**

The PSISs are palpated bilaterally, and the relative heights are assessed. The patient is asked to bend forward as far as possible, with the examiner continuing to palpate the PSISs. A positive finding is present if the examiner visualizes a change in the relative relationship of the PSIS in the fully-forward bent position. This is visualized as one PSIS moving further in a cranial direction than the other. If a positive finding is detected, the positive side is determined as the PSIS that moves more in a cranial direction between the starting and ending positions.

**5. Gillet’s Test (also known as the Stork Test):**

The patient stands with the feet about 12 inches apart. The examiner places one thumb under the PSIS on the side being tested. The other thumb is placed over the S<sub>2</sub> spinous process. The patient is instructed to stand on one leg and flex the other hip and knee, bringing the leg towards the chest. The examiner continues to palpate the PSIS on that side. The test is positive if the PSIS fails to move posterior and inferior with respect to S<sub>2</sub>.

**IV. Seated Examination**

**1. Pelvic Landmarks:**

With the patient seated, the relative heights of the PSIS and iliac crests are determined by palpation. The same options used with the standing assessment of pelvic landmarks are used.

To assess the relative heights of the PSIS in sitting, the patient is seated on a level plinth with the skin area around the PSISs exposed and with the feet comfortably supported by a stool such that the hips and knee are in approximately 90° of flexion. The examiner kneels behind the plinth. The PSISs are palpated bilaterally, and the



PSISs are assessed for relative symmetry. The examiner allows sufficient distance from the patient in order to be able to extend the elbows during the measurement. A positive finding is present if the examiner visualizes a difference in static symmetry of the PSISs.

## **2. Seated Flexion Test:**

With the patient seated and the feet supported such that the hips and knees are flexed approximately 90°. The examiner palpates the PSIS and assesses the relative height bilaterally. The patient is instructed to bend forward as far as possible while the examiner continues to palpate the PSIS. Similar to the standing flexion test, a positive finding is present if a change in the relative relationship of the PSIS is found in the fully-forward bent position (one PSIS moves further in a cranial direction than the other). The side that moves further cranially is designated as the side of the positive test.

## **V. Supine Examination**

### **1. Straight Leg Raise:**

The straight leg raise test is performed to measure the amount of motion available. The patient is supine with the hips and knees extended. The inclinometer is positioned on the tibial crest just below the tibial tubercle. The inclinometer is zeroed. The examiner then passively lifts the straight leg to the maximum tolerated straight leg raise (not the onset of pain), and the degree of motion is recorded.

### **2. Bilateral SLR:**

The bilateral SLR is used in the Physical Impairment Index. The patient is supine with the knees extended. The patient is asked to lift both legs together six inches off the examining surface and hold that position for 5 seconds. The examiner should not count aloud or offer encouragement. The patient may not use the hands to lift the legs. If the patient is unable to maintain the lifted position for 5 seconds, the test is positive.

### **3. Active Sit-Up:**

The active sit-up is used in the Physical Impairment Index. The patient is supine with the knees flexed to 90° and the soles of the feet flat on the examining surface. The examiner should hold the patient's feet with one hand. The patient is instructed to reach up with the fingertips of both hands to touch (not hold) both knees, and hold that position for 5 seconds. The examiner should not count aloud or offer encouragement. If the patient is unable to maintain the position for 5 seconds, the test is positive.

### **4. Supine Long-Sitting Test:**

The supine long-sitting test is a SIJ test that compares apparent leg lengths in the supine and long-sitting positions. With the patient in the supine position, the lengths of the inferior aspects of both medial malleoli will be examined. In the supine position, the finding of a shorter leg suggests a posteriorly rotated innominate on that side, however this is not confirmatory. While the examiner holds the medial malleolus with the thumbs, the patient is instructed to come to a long-sitting position. Any apparent lengthening of the short leg confirms what is perceived as a posteriorly rotated innominate on that side. A positive finding is present if the examiner visualizes a difference between the supine and long-sitting position of the thumbs. If a positive finding is detected, the positive side will be recorded as the side that was shorter in the supine position. However, to keep it simple, simply record the relative position of the malleoli in each position. For example, if you observe the left leg to be short in supine, mark "Short left." Then when you have them come to the long sitting position, mark what happens with respect to the left side (i.e. "Longer left", "Equally short left", or "Even shorter left"). If you observe the malleoli to be level in supine, then choose either side to mark when you have them come to the long sitting position if you observe asymmetry in this position. By recording it in this fashion, you do not have to be concerned about which side is positive or negative.

## **VI. Prone Examination**

### **1. Spring Test:**

Spring testing is performed over the spinous processes of the lumbar vertebrae. Spring testing is both a provocation test and a test of segmental mobility. The following options are available for each level tested:

- Normal Mobility - Passive mobility is judged to be normal.
- Hyper/Hypomobile - Judgments based on the passive mobility of the tested segment relative to adjacent segments and the expectation of the examiner. One of the two options may be selected.
- No Pain - No painful symptoms are produced.
- Pain - Judgment based on the provocation of pain. Local refers to pain produced directly under the examiner's hand, whereas distant pain refers to provocation at an anatomical area not directly under the examiner's hand. One of the two options may be chosen.

Spring testing is performed by placing the hypothenar eminence of the hand over the spinous process of the segment to be tested. With the elbow and wrist extended, the examiner applies a gentle but firm, anteriorly-directed pressure on the spinous process. Interpretation of whether a segment is hypomobile should be based on the examiner's anticipation of what normal mobility would feel like at that level and compared to the mobility detected in the segment above and below. In previous studies of similar subjects, it was unusual for examiners not to identify at least one hypomobile segment.

The SI is tested with palpation of the Sacral Sulcus in which the examiner palpates with firm pressure in the region directly medial to the PSIS. This is a provocation test and the presence of pain is judged for both sides.

### **2. Spinal Tenderness:**

Spinal tenderness is used in the Physical Impairment Index. The patient is prone. Superficial tenderness to light skin pinch is assessed first. The patient is asked, "Is that painful?" Any response other than "no" is a positive for spinal tenderness. If superficial tenderness is present, it precludes the assessment of deep tenderness. If superficial tenderness is not present, deep tenderness is assessed by placing firm pressure with the ball of the thumb over the spinous processes and inter-spinous ligaments within 1 cm of the midline from T<sub>12</sub> to S<sub>2</sub>. Again the patient is asked, "Is that painful?" Any response other than "no" is a positive test for spinal tenderness.

### **3. Prone knee flexion test:**

The prone knee flexion test is a dynamic test to detect the side of the innominate rotation. The patient lies prone **with the shoes on**, feet hanging off the plinth, and with the cervical spine at the midline. The examiner compares the difference in leg length by visually examining the difference in length of the left and right soles of the patient's shoes. A finding of one leg shorter than the other suggests that the innominate on the same side of the shorter leg is considered to be in posterior rotation relative to the opposite innominate, however this is not confirmatory. The examiner then passively flexes the patient's knees to 90° and observes any change in the relationship of the heel positions to each other. With passive knee flexion, an apparent increase in the leg length so that it becomes the longer of the two as the test is performed indicates a posterior innominate rotation on that side. If this leg remains apparently shorter or becomes even shorter in relationship to the other leg, it is believed that this side has an

anterior innominate rotation. A positive finding is present if the examiner visualizes a difference between prone and knee flexed position of the thumbs. The prone knee flexion test will be recorded in both the position of full knee extension and 90° of knee flexion. To keep it simple, simply record the relative position of the malleoli in each position. For example, if you observe the left leg to be short in full extension, mark "Short left." Then when you flex the knees, mark what happens with respect to the left side (i.e. "Longer left", "Equally short left", or "Even shorter left"). If you observe the malleoli to be level in full extension, then choose either side to mark when you flex the knees to 90° if you observe asymmetry in this position. By recording it in this fashion, you do not have to be concerned about which side is positive or negative.

#### **4. Measurement of hip IR and ER:**

The patient lies prone with the shoes on, and with the cervical spine at the midline. The examiner places the opposite leg of the leg to be measured in 30° of hip abduction to enable the tested hip to be freely moved into external rotation. The lower extremity of the side to be tested is kept in line with the body, and the knee on that side is flexed to 90° with the ankle in the neutral position, and the leg in the vertical position. The inclinometer is first zeroed on a vertical surface and then placed on the distal aspect of the fibula in line with the bone. The leg should be oriented in such a fashion that the inclinometer reads zero degrees. Measurement of hip IR (hip rotated in a lateral direction [leg moved toward the edge of the plinth] and ER (hip rotated in a medial direction [leg moved toward the middle of the table]) is recorded at the point in which the pelvis first begins to move. The measurement should be recorded bilaterally.

## **ASSIGNMENT OF SUBJECT ID**

Once the patient completes the Informed Consent document, the screening examination is completed, and the baseline physical examination is completed, assign the patient a Subject ID. This number serves as the identifier for all of that subject's study records. Assign subject ids in a consecutive order as subjects are enrolled into the study. In other words, just take the next folder on top of the stack. Do not skip subject ids for any reason.

## **TRANSFER OF FORMS FROM BASELINE EXAMINATION TO APPROPRIATE FOLDER:**

Don't forget that once the patient completes the Informed Consent document, the screening examination is completed, and the baseline physical examination is completed, place the forms from the Baseline Examination into the appropriate location (subject's individual masked folder or the unmasked folder). See p. 1 if you have any questions about the appropriate folder for each form.

## **RANDOMIZATION**

When the folder is obtained with the Subject ID, the therapist should open the envelope that sits in the front of the subject's folder. Notify the subject of the group assignment, and record the name of the therapist who randomized the subject and the date on the label. Place the label back inside the envelope, and place the entire envelope and its contents in the subject's study folder. At this point, the therapist should peel the forms for the "Baseline Examination and/or Treatment Session Number: 1" off the top of the stack and provide the appropriate treatment based on the group to which the subject was randomized.

## **TREATMENT PROCEDURES**

### **Exercise Group**

Subjects will complete an exercise program consisting of an aerobic component and a strengthening program in the physical therapy clinic for sessions #1-5 (all sessions). Subjects in this group will not receive manipulation. For the aerobic component, subjects will begin with a goal of 10 minutes of aerobic exercise on either a stationary bike or treadmill at a self-selected pace. Progression of the aerobic component will be performed at the therapist's discretion. Immediately following the aerobic component, subjects will complete the strengthening program (See exercise handout). Subjects need to be instructed in the exercises by the treating physical therapist during the first treatment session and then monitored throughout their participation in the study. Although a physical therapy assistant or technician may monitor the exercise program, it is important the physical therapist make contact with the subject during every session and be available to answer any questions or provide further instruction in the proper techniques of the exercise program. Subjects will also be asked to complete the strengthening program once per day on the days they do not complete the exercise program during the physical therapy session. Subjects will self-report their compliance with the exercise program in an exercise log. The aerobic component will not be included in the home exercise program.

### **Manipulation + Exercise Group**

Subjects in the manipulation + exercise group will initially receive manipulation and a range of motion (ROM) exercise (supine pelvic tilt) only for the first two treatment sessions. Beginning on the third session, these subjects will receive the same treatment program outlined above for the exercise group, and the manipulation and ROM exercises they completed during the first two sessions will be discontinued. For the first two sessions in which manipulation is to be performed, the manipulation technique will be performed before the pelvic tilt exercise.

To perform the manipulation, the subject is supine. The therapist stands on the side opposite of that to be manipulated. The subject is passively moved into side-bending towards the side to be manipulated. The subject interlocks the fingers behind his or her head. The therapist passively rotates the subject, careful to maintain the

subject's side-bending, then delivers a quick thrust to the ASIS in a posterior and inferior direction. The side to be manipulated will be the more symptomatic side based on the subject's self-report. If the subject cannot specify a more symptomatic side, the therapist may select either side for manipulation. After the manipulation is performed, the therapist will note whether or not a cavitation (i.e. "a pop") was either heard or felt by the therapist or subject. If a cavitation is experienced, the therapist will proceed to instruct the subject in the hand-heel rock exercise. If no cavitation is produced, the subject will be repositioned and the manipulation will be attempted again. If no cavitation is experienced, the therapist will attempt to manipulate the opposite side. A maximum of two attempts per side will be permitted. If no cavitation is produced the therapist will proceed to instruct the subject in the pelvic tilt exercise.

The pelvic tilt exercise will be completed immediately in the physical therapy clinic immediately after the manipulation. Subjects are asked to lie on their back and bend the hips and knees so that their feet are flat on the surface. Subjects then attempt to flatten their back on the table by slightly "drawing in" their stomach and rotating the hips backwards without holding their breath. The motion is to be performed in a pain-free range. Subjects will be instructed to perform a set of 10 repetitions in the clinic during the first and second sessions after manipulation and will be instructed to perform 10 repetitions of the exercise 3-4 times daily until the beginning of the third treatment session, when they will complete the same strengthening and aerobic exercise program as those subjects in the exercise group. At the beginning session #3, the therapist should instruct subjects in this group in the full exercise program (to include the aerobic exercise component). Subjects will self-report their compliance with the exercise program in an exercise log. **Essentially, beginning on session #3, the groups become identical. Subjects in this group will no longer receive manipulation after the first two sessions.**

### **Other Treatment-Related Instructions**

There are a total of five sessions over the course of a four-week period in which the subject will be treated in physical therapy. The subject will be treated twice in the first week and then once a week for the next three weeks. The first treatment session would ideally occur on the same day in which the Baseline Examination and the randomization is conducted. However, if time does not allow therapists to provide treatment on this day, reschedule the subject for the next day, if possible, or within 2 days at the most. Otherwise, the physical examination findings are likely to change, and perhaps the classification status could possibly be different due to changes that occur with the passing of time. To be clear as to what constitutes the first session, begin counting sessions on the first session in which the treatment to which the subject was randomized is provided. In other words, in the event the baseline physical examination and first treatment session do not occur on the same day, session #1 would coincide with the session in which the treatment is provided, not the session in which the baseline physical examination was conducted. In these cases, subjects will actually receive a total of 6 sessions (1 for the Baseline Examination and randomization and then 5 treatment sessions) rather than 5. The first treatment session is also the session in which the instruction for the home exercise program should be given. In other words, for subjects who begin to receive treatment 1-2 days after the baseline physical examination, they should not be instructed to perform the home exercise component of the treatment program until the day after their first treatment session, not during the 1-2 day interim period between the baseline physical examination and the first treatment session.

The subject may continue other forms of exercise (i.e. walking/jogging program) they had previously been conducting prior to their participation in this study. The one exception to this is if the subject is performing other exercises specifically for their low back (i.e. perhaps exercises prescribed to them previously during an episode of care in physical therapy). These exercises should be discontinued, and only the exercises included in the exercise program should be performed during the subject's participation in this study. The therapist should also instruct them not to begin any new forms of exercise during their participation in this study. Finally, attempt to avoid any co-interventions if at all possible. For example, do not apply a moist hot pack prior to the exercise program or apply an ice pack after the exercise program. Obviously, provide whatever care is necessary if the subject experiences some

type of adverse reaction to the manipulation or exercise program. However, be sure to document any such treatment on that day's treatment form.

### **Follow-Up Examinations for Session #3 and #5**

There are two simple follow-up physical examinations (at Session #3 and Session #5) where only a few tests are performed. These follow-up examinations should be performed by the subject's therapist.

### **SUBJECT PAYMENT**

Subjects will be paid \$25.00 for initial enrollment (complete Informed Consent document and deemed eligible for the study) and \$25.00 each for completing the second, third, and fourth weeks of the study, for a total of \$100.00 compensation. There is a payment form at the back of each subject's folder for you to document the degree of completeness of the subject's participation. Subjects will be paid based on your documentation on this form. Subjects will receive one check at the end of their participation in the study for the degree of the study completed. Remind subjects that payment usually takes from 6-8 weeks from the time the therapist faxes me the completed payment form. **To ensure subjects receive prompt payment, these forms (unlike the other forms), should be faxed to me on the same day they are completed to John Childs at (412) 383-6629.**

### **DATA MANAGEMENT**

Package completed study folders in a box and mail to me at the address listed below using FedEx or UPS 2nd Day Air. Make sure the folders will not be able to excessively move inside the box, or it could become difficult to re-organize the data back to the correct subject. Also, if possible, avoid using any of the Next Day Air options, as the cost significantly increases. Be sure to write down the tracking number so we can track the package on-line if necessary. Thanks. Mail to the following address:

John D. Childs  
508 Thurber Drive  
Schertz, TX 78154-1146

Home Ph: (210) 566-0889  
E-mail: childsjd@bigfoot.com

**Note:** Be sure to keep your receipt. Fax your copy of the billing label to me at (210) 292-7991. I will reimburse you once I receive a copy.

### **Ordering of Forms**

#### **Contents of the masked folder**

The forms will have been in chronological order throughout the study to make it easy for therapists to just peel forms off the top. However, before mailing, one of the keys will be to organize each of the folders according to the way it's outlined below. Instead of the folders being organized chronologically (i.e. all the data for session 1, then session 2, session 3, etc.), it will be much easier for entering if all of the similar information is grouped together (i.e. all the Oswestrys in order, all the FRIs in order, etc.). Feel free to call me if you have any questions on how to do this. Place the forms in the following order:

1. Pain Diagram and Rating forms (Sessions #1, 3, and 5)
2. Oswestry Disability Questionnaire forms (Sessions #1-5)
3. Functional Rating Index forms (Sessions #1-5)
4. Fear-Avoidance Beliefs Questionnaire forms (Sessions #1, 3, and 5)

5. Patient Global Rating of Change forms (Sessions #2, 3, and 5)
6. Therapist Global Rating of Change forms (Session #2, 3, and 5)
7. Demographic Information form (Session #1)
8. Immediate Post-Treatment Follow-Up Questionnaire form (Session #5)
9. Physical Examination forms (Sessions #1, 3, and 5)
  - a. Session #1: Baseline Physical Examination form
  - b. Sessions #3 and 5: Follow-Up Physical Examination forms
10. PT Session Treatment forms (Sessions #1-5)
11. Patient Exercise Log
12. Randomization envelope with index card inside the envelope
13. Screening Examination form

**Contents of the unmasked folder**

These forms do not have to be in separate folders for each subject. If you wish, group all of this information together in one large stack, so long as all of the information for a given subject is grouped together.

1. Informed consent document
2. Subject ID-Name Link form
3. Subject Payment form