

## SUMMARY OF PROMIS WAVE 2 PROTOCOLS

### Pain & Depression Protocol Summary Information: Pain Cohort

**Organization's Unique Protocol ID:** 07-04

**Brief Title:** Validating PROMIS Instruments in Depression and Back and Leg Pain

**Study Type:** Observational

**Human Subjects Review:** Submitted, approved

**Board approval number:** 33606 J  
09/02/2008

**Board Name:** University of Washington Human Subjects Division

**Board Affiliation:** University of Washington Human Subjects Division

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**Oversight Authorities:** United States: Institutional Review Board

**Sponsor:** National Institutes of Health

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**Brief Summary:** The University of Washington Center on Outcomes Research in Rehabilitation (UWCORR) is a member of the Patient Reported Outcomes Information System (PROMIS) Network. PROMIS is funded by the NIH Roadmap initiative working to improve the efficiency and accuracy of measuring patient-reported outcomes. UWCORR works collaboratively with five research sites

(Stanford University, Duke University, State University of New York, University of Pittsburgh, and University of North Carolina) and a Statistical Coordinating Center (NorthShore University HealthSystem).

Collectively, the goal of the PROMIS Network is to create a publicly available system that can be periodically added to and modified and that allows clinical researchers to access a common repository of items and computerized adaptive tests. The first step in achieving this goal was to build item pools and develop core questionnaires that measure key health outcome domains that are manifested in a variety of disabilities and chronic conditions. The resulting six item banks cover the domains of pain, fatigue, social health, physical functioning, emotional functioning, and sleep-wake functioning.

The next step in this process is to validate the PROMIS item banks and to examine their utility as computerized adaptive tests (CATs) with individuals diagnosed with a variety of chronic conditions and disabilities. At UWCORR, we will recruit patients with back and leg pain and treated with epidural steroid injections. This protocol is aimed at comparing the psychometric properties of the PROMIS item banks with non-PROMIS 'gold standard' instruments, diagnostic data, and medical records. We will compare de-identified data from this study with de-identified data from other PROMIS research centers.

<b>Overall Recruitment Status:</b>	Recruiting
<b>Study Start Date:</b>	07/23/2008
<b>Study Completion Date:</b>	07/31/2009
<b>Study Design:</b>	Case-only
<b>Time Perspective:</b>	Prospective
<b>Enrollment:</b>	Target: 185
<b>Number of Groups/Cohorts:</b>	1
<b>Group/Cohort Label:</b>	Patients with back and leg pain (sciatica) scheduled for and received an epidural steroid injection
<b>Intervention Type:</b>	This is an observational study in which outpatients receive procedural intervention(s).
<b>Conditions or Focus of Study:</b>	Back and Leg pain (sciatica)

**Study Population Description:** Patients with back and leg pain scheduled for epidural steroid injections that have had pain for at least 6 weeks.

**Sampling Method:** Non-probability sample

**Eligibility Criteria:** Inclusion criteria:

- 18+ years old
- Have back pain with sciatica for at least 6 weeks
- Scheduled for an epidural steroid injection (and did not receive ESI in past 3 months)

Exclusion criteria:

- NOT scheduled for ESI
- Has dementia or other cognitive impairments that would interfere with questionnaire completion
- Received an ESI within the last 3 months
- History of prior lumbar surgery in the last year, unstable neurological symptoms (i.e. experiencing bowel or bladder incontinence, numbness in groin area, new or worsening weakness in legs or new numbness or tingling in legs), cauda equina syndrome, cancer, spinal cord injury, vertebral fractures or MS

**Gender:** Both

**Age Limits:** Minimum age: 18 years  
Maximum age: N/A

**Facility:** Harborview Medical Center: UW Medicine Spine Clinic.  
Seattle, WA 98104, USA

University of Washington Medical Center: UW Sports and Spine Physicians, Seattle, WA 98105, USA

**Recruitment Status:** Recruiting

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