

## SUMMARY OF PROMIS WAVE 2 PROTOCOLS

### Arthritis Protocol Summary Information

**Organization's Unique Protocol ID:** 07-01

**Brief Title:** Initial Validation Of PROMIS Physical Function/Disability Scales In Rheumatoid Arthritis (RA)

**Official Title:** Initial Validation Of PROMIS Physical Function/Disability Scales In Rheumatoid Arthritis (RA)

**Study Type:** Observational

**Human Subjects Review:** Submitted, approved

**Board approval number:** 08/27/2008

**Board Name:** Administrative Panel on Human Subjects in Medical Research

**Board Affiliation:** Stanford Human Research Protection Program (HRPP)

**Board Contact:** Ronald L. Ariagno, MD, Chair  
Panel on Medical Human Subjects  
650-724-7541  
Research Compliance Office  
1215 Welch Road, Modular A  
Stanford CA, 94305-5401

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

**Sponsor:** National Institutes of Health

**Collaborators:** Stanford University, QualityMetric Inc.

**Brief Summary:** We will conduct initial validation studies of the PROMIS physical function, fatigue, and pain impact short forms in patients with rheumatoid arthritis (RA).

**Overall Recruitment Status:** Enrolling by invitation: participants are being (or will be) selected from a predetermined population

**Study Start Date:** June 2008

**Study Completion Date:** July 2009

<b>Study Design: (Observational Study Model)</b>	Cohort (randomized to questionnaire order)
<b>Time Perspective:</b>	Prospective
<b>Enrollment:</b>	Target: 525
<b>Number of Groups/Cohorts:</b>	1
<b>Primary and Secondary Outcome Measures</b>	
<b>Primary Outcome Measure:</b>	Primary outcome: ability of Legacy or PROMIS instruments to detect change over 6 and 12 months in rheumatoid arthritis: (a) when an anti-TNF drug has been begun, (b) when the patients reports improvement over the prior period, (c) when the patient global has improved over the prior period.
<b>Group/Cohort Label:</b>	Legacy HAQ-DI first, PROMIS 20-item short form first
<b>Group/Cohort Description:</b>	Rheumatoid arthritis patients, before and after comparisons of physical function using Legacy HAQ-DI and PROMIS 20-item short forms; all in cohort receive both questionnaires at the same administration, with the randomized to eliminate order effects
<b>Intervention Type:</b>	Other – comparative questionnaire study for sensitivity to change of alternative questions
<b>Conditions or Focus of Study:</b>	Rheumatoid arthritis
<b>Study Population Description:</b>	Patients from 3 sources will be included in the study: ARAMIS RA cohort, Stanford RA registry, and Stanford RA clinical trials patients
<b>Sampling Method:</b>	Probability Sample
<b>Eligibility Criteria:</b>	Inclusion: rheumatologist-diagnosed RA; meets one of the conditions for treatment intensification as described in the protocol; ability to read, write, speak English, ability to understand and provide informed consent Exclusion: unable/unwilling to complete questionnaires
<b>Gender:</b>	Both
<b>Age Limits:</b>	Minimum age: 18 years Maximum age: N/A
<b>Facility:</b>	Stanford University School of Medicine 1000 Welch Rd. Suite 203 Palo Alto, CA 94304 USA

650-725-4612

**Recruitment Status:** Enrolling by invitation

**Facility Contact:** Karen Fisher, Research Process Manager  
Kfisher@stanford.edu

**Investigators:** James F. Fries, MD  
Site Principal Investigator

**Central Contact:** Deborah Ambrosini  
[dka@stanford.edu](mailto:dka@stanford.edu)

**Chronic Obstructive Pulmonary Disease (COPD) Protocol Summary Information**

**Organization's Unique Protocol ID:** 07-02

**Brief Title:** Validation of PROMIS Banks with COPD Exacerbations

**Official Title:** Validation of PROMIS Banks with COPD Exacerbations

**Study Type:** Observational

**Human Subjects Review** Submitted, approved

**Board approval number:** 08-0138

**Board Name:** University of North Carolina Institutional Review Board

**Board Affiliation:** University of North Carolina

**Board Contact:** Medical School Building 52  
105 Mason Farm Road  
CB # 7097  
Chapel Hill, NC 27599-7097  
Telephone: 919-966-3113  
Fax: 919-966-7879

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

**Sponsor:** National Institutes of Health

**Collaborators:** University of Pittsburgh, Duke University, NorthShore University Health System

**Brief Summary:** This is a prospective, longitudinal study of adult patients with Chronic Obstructive Pulmonary Disease (COPD), patients who will be enrolled when their COPD is considered clinically stable or during an acute

exacerbation. This design will allow both within-person and between person comparisons by exacerbation experience. Comprehensive clinical and patient-reported assessments will be performed at baseline and at 3 months (end of study). Subsets of items will be administered by interactive voice response (IVR) over the course of the study to measure changes in key symptoms over the course of recovery from an exacerbation. A subset of patients will be interviewed at the end of the study to assess content validity of PROMIS items in this patient population.

With such a study design, we will be able to evaluate the validity of the PROMIS items in this patient population under acute and stable conditions and evaluate responsiveness of several PROMIS item banks under conditions of known change in an underlying chronic disease. We will also evaluate stability of sub-domains that are not hypothesized to change with COPD exacerbations.

#### Objectives

To assess the reliability and content and construct validity (including responsiveness to change) of PROMIS instruments in patients with COPD during stable state and during acute exacerbations of COPD. Specifically, we have the following aims:

1. To evaluate the reliability (internal consistency, test-retest reliability) of the PROMIS Computer Adaptive Tests (CATs) / short forms.
2. To compare CAT / short form scores in the PROMIS domains with clinical assessments of COPD patients when the patient is initially considered stable. Clinical assessments will include COPD GOLD Stage, forced expiratory volume during the first second (FEV1), and 6-minute walk distance.
3. To evaluate changes in CAT/short form scores in the PROMIS domains from the nadir with an exacerbation compared to within person stable disease state.
4. To compare responsiveness to change of the PROMIS CAT/short form scores with the comparable subscale scores from the St. Georges Respiratory Questionnaire (SGRQ) and to estimate minimally important differences (MID) for the domains of the PROMIS CAT/short forms.
5. To compare results from 7 day recall period obtained from PROMIS CAT/short form scores to the results obtained from the EXACT-PRO (daily

- diary approach with 1 day recall period) administered during the first 7 days of the study.
6. To perform a qualitative review for content validity of the PROMIS items.
  7. To explore the impact of literacy on computer based testing as measured by missing data, rate, variance and differences in mean PROMIS CAT/short form scores.

We hypothesize the following with respect to the above objectives:

1. The PROMIS CATs and short forms will be internally consistent and have good test-retest reliability.
2. There will be significant correlations between PROMIS scores and clinical assessment in both groups.
3. There will be significant improvement (positive slope) in the PROMIS measures in COPD patients during recovery from exacerbation to a stable period.
4. PROMIS items will have comparable responsiveness to the SGRQ and that there will be significant improvement in PROMIS measures following the exacerbation.
5. Patients will have similar results on the 7 day recall PROMIS items compared to EXACT-PRO items.
6. Qualitative data from cognitive interviews of patients with COPD will provide evidence in support of content validity of PROMIS items

<b>Overall Recruitment Status:</b>	Recruiting
<b>Study Start Date:</b>	July 1, 2008
<b>Study Completion Date:</b>	June 30, 2009
<b>Study Design: (Observational Study Model)</b>	Cohort
<b>Time Perspective:</b>	Prospective
<b>Enrollment:</b>	Target: 180
<b>Number of Groups/Cohorts:</b>	2
<b>Primary and Secondary Outcome Measures</b>	Changes in scores on PROMIS measures
<b>Primary Outcome Measure:</b>	Change in scores on PROMIS measures from baseline to 3 months. Comparing patients starting in stable state to

patients having an exacerbation.

<b>Group/Cohort Label:</b>	Stable, Exacerbation
<b>Group/Cohort Description:</b>	Stable: Patients who are stable have not had a COPD exacerbation in the past 2 months Exacerbation: Patients with an exacerbation have been diagnosed and started on treatment for an exacerbation within the past 3 days.
<b>Intervention Type:</b>	None
<b>Conditions or Focus of Study:</b>	COPD
<b>Study Population Description:</b>	People presenting to primary care or specialty clinics with COPD either with exacerbation or not. People admitted to the hospital with a COPD exacerbation.
<b>Sampling Method:</b>	Non-probability sample
<b>Eligibility Criteria:</b>	Inclusion: <ul style="list-style-type: none"><li>• Gender: Male or Female (We will attempt to enroll approximately 50% men/women)</li><li>• Age: <math>\geq 40</math> years</li><li>• Diagnosis: An established clinical history of COPD in accordance with the GOLD definition (Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease with some significant extrapulmonary effects that may contribute to the severity in individual patients. Its pulmonary component is characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases.)</li><li>• A history of smoking (at least 10 pack/year history)</li><li>• Access to and able to communicate on a touch tone telephone</li><li>• Read and speak English</li><li>• Able to see and interact with a computer screen, mouse and keyboard</li><li>• Informed Consent: A signed and dated written informed consent prior to study participation</li><li>• For those enrolled into the exacerbation group, patients must have been diagnosed with an exacerbation within 3 days of the day of enrollment.</li><li>• For those enrolled in the stable state group, the patient will be considered stable if he or she has been exacerbation-free for a minimum of 2 months prior to enrollment.</li></ul>

Exclusion:

- A subject will not be eligible for inclusion in this study if in the investigator's opinion the patient has any concurrent medical or psychiatric condition that may preclude participation in this study or completion of self-administered questionnaires (e.g., moderate to severe dementia and/or severe, uncontrolled schizophrenia, or other condition that would render them unable to complete a questionnaire).
- History of asthma without co-existent COPD as the primary diagnosis.
- Patients experiencing a current heart failure exacerbation. A diagnosis of heart failure is not in itself an exclusion criterion.

**Gender:**

Both

**Age Limits:**

Minimum age: 40 years  
Maximum age: N/A

**Facility:**

University of North Carolina at Chapel Hill  
Chapel Hill, NC, USA

University of Pittsburgh and the Pittsburgh VA  
Pittsburgh, PA, USA

NorthShore University HealthSystem  
Evanston, IL, USA

**Recruitment Status:**

Recruiting

**Facility Contact:**

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**Investigators:**

UNC:  
Darren DeWalt, MD, MPH, Site Principal Investigator  
Debra Irwin, PhD, Co-Investigator  
James Donohue, MD, Co-Investigator

Pittsburgh:  
Charles Atwood, MD, Site Principal Investigator

Duke:  
Neil MacIntyre, MD, Site Principal Investigator

NorthShore University HealthSystem:  
Susan Yount, PhD, Site Principal Investigator

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### **Congestive Heart Failure (CHF) Protocol Summary Information**

**Organization's Unique Protocol ID:** 07-03

**Brief Title:** Validating PROMIS Instruments in Congestive Heart Failure Patients Receiving a Heart Transplant

**Official Title:** Validating PROMIS Instruments in Congestive Heart Failure Patients Receiving A Heart Transplant

**Study Type:** Observational

**Human Subjects Review** Submitted, approved

**Board approval number:** 10/02/2008

**Board Name:** The Duke University Health System Institutional Review Board for Clinical Investigations (DUHS IRB)

**Board Affiliation:** Duke University Health System

**Board Contact:** John Harrelson, M.D.  
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[harre004@mc.duke.edu](mailto:harre004@mc.duke.edu)  
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Durham, NC 27710

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

**Sponsor:** National Institutes of Health

**Collaborators:** Stanford University and the University of Pittsburgh

**Brief Summary:** The purpose of this research study is to learn about the experience and impact of having Congestive Heart Failure (CHF). In particular, we hope to develop better questionnaires that can measure heart failure patients' quality-of-life.

**Detailed Description (if desired):** This project will assess the validity (including responsiveness) of selected Patient Reported Outcome Measurement Information System (PROMIS) instruments in patients with severe chronic heart failure (CHF) who receive heart transplants. The following is a list of goals for this project:

- To estimate the responsiveness of PROMIS domain

scores by comparing scores in patients with severe heart failure before and after a clinically significant event (heart transplant). The specific PROMIS domains assessed are physical functioning, fatigue, satisfaction with discretionary social activities, depression, and global health.

- To estimate the responsiveness of a disease-specific PRO measure, the Kansas City Cardiomyopathy Questionnaire (KCCQ) and the Medical Outcomes Study Short Form-36 Vitality subscale (SF-36v2) and the Patient Health Questionnaire (PHQ-2).
- To collect cross-sectional and longitudinal data on traditional clinical measures of heart failure outcome (6 minute walk test and NYHA class) that can inform the definition of a minimally important difference (MID) for the PROMIS domains of physical functioning, fatigue, satisfaction with discretionary social activities, depression, and global health.

<b>Overall Recruitment Status</b>	Not yet recruiting
<b>Study Start Date:</b>	Anticipated December 2008
<b>Study Design: (Observational Study Model )</b>	Cohort
<b>Time Perspective:</b>	Prospective
<b>Enrollment:</b>	Target: 150
<b>Number of Groups/Cohorts:</b>	1
<b>Group/Cohort Label:</b>	Heart transplant recipients
<b>Group/Cohort Description:</b>	To be eligible, heart failure had to represent the greatest medical limitation on daily function for the patient in the judgment of the attending cardiologist.
<b>Intervention Type:</b>	Other; this is an observational study only. No treatment will be assigned to these patients through this protocol. The intervention decision (heart transplant surgery) will be made solely by patients and their physicians and reported to us. Usual clinical care for patients in this study will not be altered.
<b>Conditions or Focus of Study:</b>	Congestive Heart Failure
<b>Study Population Description:</b>	Participants will be recruited through heart transplant program registries and in consultation with practicing cardiologists at Duke University, Stanford University and the University of Pittsburgh.

**Sampling Method:** Non-Probability Sample

**Eligibility Criteria:** Inclusion criteria: To be eligible, heart failure had to represent the greatest medical limitation on daily function for the patient in the judgment of the attending cardiologist.

1. Must be 18 years old or older
2. Ability to read, write, and speak in English
3. Ability to understand and provide informed consent
4. No current diagnosis of psychosis or dementia
5. Placement on heart transplant registry (awaiting heart transplant surgery)

**Gender:** Both

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

**Facility:** Duke University Medical Center  
Durham, NC  
USA

Stanford University  
Palo Alto, CA  
USA

University of Pittsburgh Medical Center  
Pittsburgh, PA  
USA

**Recruitment Status:** Not yet recruiting

**Facility Contact:** Felicia L. Graham, MBA  
919-668-8670  
Felicia.graham@duke.edu

**Investigators:** Kevin P. Weinfurt, Ph.D.  
Role: Site Principal Investigator

**Central Contact:** Felicia L. Graham, MBA  
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**Pain & Depression Protocol Summary Information: Depression Cohort**

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

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

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

**Study Type:** Observational

**Human Subjects Review** Submitted, approved

**Board approval number:** PRO07070241

**Board Name:** University of Pittsburgh Institutional Review Board

**Board Affiliation:** University of Pittsburgh Institutional Review Board

**Board Contact:** 3500 Fifth Avenue  
Ground Level  
Pittsburgh, PA 15213  
(412) 383-1480  
(412) 383-1508 (fax)  
<http://www.irb.pitt.edu>

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

**Sponsor:** National Institutes of Health

**Collaborators:** The Patient-Reported Outcomes Measurement Information System (PROMIS) is a National Institutes of Health (NIH) Roadmap initiative to develop a computerized system measuring patient-reported outcomes in respondents with a wide range of chronic diseases and demographic characteristics. PROMIS was funded by cooperative agreements to a Statistical Coordinating Center (NorthShore University HealthSystem, PI: David Cella, PhD, U01AR52177) and six Primary Research Sites (Duke University, PI: Kevin Weinfurt, PhD, U01AR52186; University of North Carolina, PI: Darren DeWalt, MD, MPH, U01AR52181; University of Pittsburgh, PI: Paul A. Pilkonis, PhD, U01AR52155; Stanford University, PI: James Fries, MD, U01AR52158; Stony Brook University, PI: Arthur Stone, PhD, U01AR52170; and University of Washington, PI: Dagmar Amtmann, PhD, U01AR52171). NIH Science Officers on this project are Deborah Ader, Ph.D., Susan Czajkowski, PhD, Lawrence Fine, MD, DrPH, Louis Quatrano, PhD, Bryce Reeve, PhD, William Riley, PhD, and Susana Serrate-Sztein, PhD. See the web site at [www.nihpromis.org](http://www.nihpromis.org) for additional information on the PROMIS cooperative group.

**Brief Summary:**

In the first three years of its existence, the PROMIS network developed item banks for measuring patient-reported outcomes including pain, fatigue, emotional distress, physical function, sleep-wake function, and social functioning. During the item banking process, the PROMIS network conducted focus groups, cognitive interviews, and lexile (reading level) analyses to refine the meaning, clarity, and literacy demands of all items. The item banks were administered to over 20,000 respondents and calibrated using models based on item response theory (IRT). Using these IRT calibrations, CAT algorithms were developed and implemented.

In order to validate the item banks and to examine their utility as computerized adaptive tests (CATs), the PROMIS network has designed a series of studies that will allow us to examine the attributes of the measures in “real-world” clinical environments. This protocol is aimed at comparing the psychometric properties of the PROMIS item banks with non-PROMIS “gold standard” instruments currently used in our respective fields (pain and mental health). In this context, note that the proposed study is not intended to evaluate treatment effectiveness, and no control group has been included. The main consideration has been to design a study involving ecologically valid treatments with established efficacy that can be administered and evaluated over the short term (i.e., 3 months). Regardless of their impact in the aggregate, such treatments will generate considerable variability in individual outcomes, and this heterogeneity is optimal for examining relevant psychometric issues. The psychometric issue of greatest concern is the validity of the PROMIS item banks as evidenced in convergent and discriminant validity and responsiveness to change. We also will make initial estimates of clinically significant change as reflected in our PROMIS measures. By combining efforts of the two sites that led in the development of the item banks for emotional distress (University of Pittsburgh) and pain (University of Washington), the study will maximize total sample size and provide a fertile ground for analyses of psychometric functioning of the PROMIS banks.

In addition to psychometric questions, we will also address clinically meaningful questions related to pain, depression, and the relationship between the two. The complex relationship between pain and depression has been observed for years. Both syndromes are mutually exacerbating—pain worsens depression and depression worsens the experience of pain. The domain-related issues of greatest interest focus on the interaction

between depression and pain and its impact on treatment outcome (including changes in symptoms of both depression and pain, in acute clinical status, and in social functioning).

<b>Overall Recruitment Status:</b>	Recruiting
<b>Study Start Date:</b>	06/16/08
<b>Study Completion Date:</b>	07/31/10
<b>Study Design: (Observational Study Model )</b>	Case-only (diagnosed with major depressive disorder [MDD])
<b>Time Perspective:</b>	Prospective
<b>Enrollment:</b>	Target: 115 depressed persons
<b>Number of Groups/Cohorts:</b>	1
<b>Primary and Secondary Outcome Measures</b>	
<b>Primary Outcome Measure:</b>	Primary outcome measures: Instruments will include PROMIS computerized adaptive tests (CATs) for pain, fatigue, social functioning, depression, anxiety, anger, sleep, wake, and physical functioning, and non-PROMIS measures (conventional instruments) also administered by computer. Time frame: Assessments at baseline, 1 month, and 3-month follow-up
<b>Secondary Outcome Measure:</b>	Secondary outcome measures: We also will make judgments of clinically significant change (via diagnostic interviews) and compare these with the changes reflected in our PROMIS measures. Time frame: Assessments at baseline, 1 month, and 3-month follow-up
<b>Group/Cohort Label:</b>	Depressed adults in open treatment
<b>Group/Cohort Description:</b>	Meets DSM-IV criteria for Major Depressive Disorder. The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV; American Psychiatric Association, 2000), characterizes MDD as: An episode in which five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure. 1. Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears

tearful).

2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others).

3. Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day.

4. Insomnia or hypersomnia nearly every day.

5. Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down).

6. Fatigue or loss of energy nearly every day.

7. Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick).

8. Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others).

9. Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.

**Intervention Type:**

Other; this is an observational study in which outpatients receive uncontrolled active treatment including drug, behavioral intervention, or both.

**Conditions or Focus of Study:**

Major Depressive Disorder: DSM diagnostic codes 296.21, 296.22, 296.23, 296.31, 296.32, 296.33

**Study Population Description:**

Adults who have started treatment for an episode of Major Depressive Disorder in the last 4 months at Western Psychiatric Institute and Clinic in Pittsburgh, PA. WPIC houses the Department of Psychiatry at the University of Pittsburgh Medical Center and serves as the flagship for the UPMC Behavioral Health Network, the psychiatric specialty division of the UPMC Health System. Each year, WPIC provides more than 350,000 patient contacts in its ambulatory care sites.

**Sampling Method:**

Non-Probability Sample

**Eligibility Criteria:**

Inclusion:

- Males and females
- Age 18 or older
- Willing and able to give informed consent
- English-speaking, able to read and understand

- English
- Currently in the first 4 months of outpatient treatment at Western Psychiatric Institute and Clinic (WPIC) for major depressive disorder (MDD).
- Participants will be required to have a minimum score of 12 on the 17-item Hamilton Rating Scale for Depression

**Exclusion:**

- Lack of willingness or ability to provide informed consent
- Dementia or other cognitive impairment that would interfere with questionnaire completion
- Lifetime history of any psychotic disorder (e.g., schizophrenia, schizoaffective disorder) or bipolar disorder as evidenced in the participant's medical records or reported during the SCID interview
- Organic affective syndrome (i.e., mood disorder secondary to a general medical condition or substance-induced mood disorder)
- Current psychiatric inpatient treatment
- A history of continuous care for one year or more in the mental health care system within the prior five years (in order to eliminate patients with more chronic presentations)
- Major medical conditions that influence the central nervous system (e.g., Parkinson's disease, stroke, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), systemic lupus erythematosus (SLE), seizure disorders, etc.)

**Note:** Persons with common psychiatric comorbidities (e.g., anxiety disorders) will be included. The presence of psychiatric comorbidities will be documented.

**Gender:**

Both

**Age Limits:**

Minimum age: 18 years  
Maximum age: N/A

**Facility:**

University of Pittsburgh Medical Center  
Western Psychiatric Institute and Clinic  
3811 O'Hara St.  
Pittsburgh, PA 15213  
USA

**Recruitment Status:**

Recruiting

**Facility Contact:**

Angela Stover, M.A  
Program Coordinator

Pittsburgh PROMIS  
412-246-5551  
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**Investigators: (at protocol location)**

PI: Paul A. Pilkonis, PhD  
Co-I: Jordan Karp, MD  
Co-I: Lan Yu, PhD

**Central Contact:**

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**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

**Board Contact:**

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Human Subjects Division  
BOX 359470  
Seattle, WA 98195-9470  
206-543 0098

**Oversight Authorities:**

United States: Institutional Review Board

**Sponsor:**

National Institutes of Health

**Collaborators:**

Paul A. Pilkonis, University of Pittsburgh, PI  
Dagmar Amtmann, University of Washington, PI  
Judith Turner, University of Washington  
Janna Friedly, University of Washington  
Jordan Karp, University of Pittsburgh

Jennifer Beaumont, NorthShore University HealthSystem

Karon Cook, University of Washington  
Lan Yu, University of Pittsburgh  
Angela Stover, University of Pittsburgh  
Rana Salem, University of Washington

**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.

**Overall Recruitment Status:** Recruiting

**Study Start Date:** 07/23/2008

**Study Completion Date:** 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)
<b>Study Population Description:</b>	Patients with back and leg pain scheduled for epidural steroid injections that have had pain for at least 6 weeks.
<b>Sampling Method:</b>	Non-probability sample
<b>Eligibility Criteria:</b>	<p><u>Inclusion criteria:</u></p> <ul style="list-style-type: none"> <li>• 18+ years old</li> <li>• Have back pain with sciatica for at least 6 weeks</li> <li>• Scheduled for an epidural steroid injection (and did not receive ESI in past 3 months)</li> </ul> <p><u>Exclusion criteria:</u></p> <ul style="list-style-type: none"> <li>• NOT scheduled for ESI</li> <li>• Has dementia or other cognitive impairments that would interfere with questionnaire completion</li> <li>• Received an ESI within the last 3 months</li> <li>• 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</li> </ul>
<b>Gender</b>	Both
<b>Age Limits:</b>	Minimum age: 18 years Maximum age: N/A
<b>Facility:</b>	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

**Facility Contact:** Harborview Medical Center  
Janna Friedly, MD  
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UWMC Sports and Spine Physicians:  
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**Investigators: (at protocol location)** Dagmar Amtmann, PhD  
Principal Investigator

**Central Contact:** Alyssa Bamer M.A.  
Research Scientist and Manager  
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**Mode of Administration Protocol Summary Information**

**Organization's Unique Protocol ID:** 07-05

**Brief Title:** Impact of Mode of Administration

**Official Title:** Investigating the Impact of Mode of Administration on Item Response

**Study Type:** Observational

**Human Subjects Review** Submitted, pending

**Board approval number:** N/A

**Board Name:** New England Institutional Review Board

**Board Affiliation:** New England Institutional Review Board

**Board Contact:** Erin Brower, MS, CIP  
Director of Operations  
New England IRB  
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**Oversight Authorities:** United States: Institutional Review Board

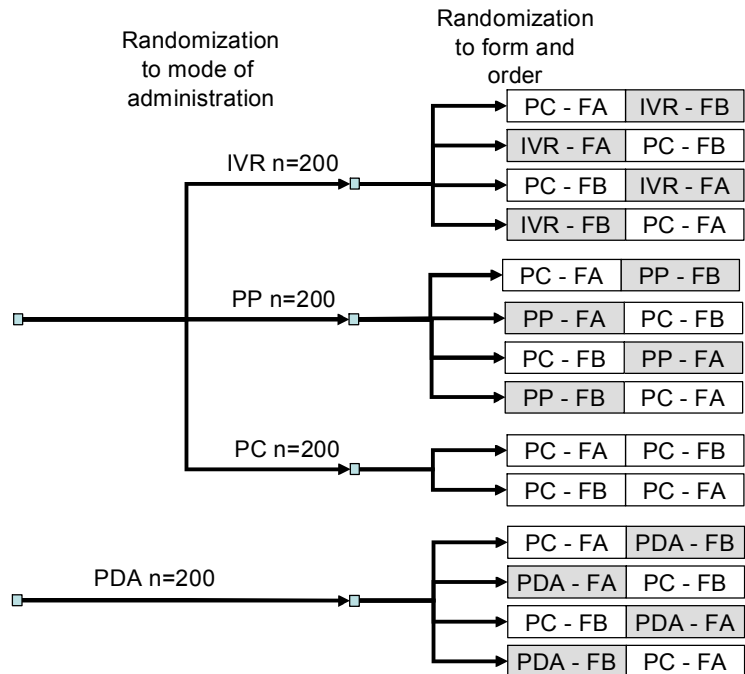
**Sponsor:** National Institutes of Health, National Institute of Arthritis and Musculoskeletal and Skin Diseases

**Collaborators:** QualityMetric Incorporated, Stony Brook University, NorthShore University HealthSystem, Stanford University

**Brief Summary:** This study is designed to examine how differences in modes of data capture affect psychometric properties and score differences and to evaluate the consistency of these results across three PROMIS health domains: emotional distress-depression, fatigue, and physical function. Four modes of administration will be compared: interactive voice response (IVR) technology, paper and pencil questionnaire, personal computer, and personal digital assistant (PDA). A total of 800 patients will be enrolled from three diagnostic groups: chronic obstructive pulmonary disease, depression, and rheumatoid arthritis. The study will test for equivalence across modes of administration, with the hypothesis that there are no mode effects; if mode effects are found, their magnitude across modes will be estimated. This network project will result in an improved understanding of the effect of assessment mode on PRO data. Guidance from this project can help in planning future PROMIS activities beyond the present PROMIS program.

**Detailed Description:** This study is designed to systematically test the impact of mode of administration on patient-reported outcomes measures included in the PROMIS item banks. It is designed as a randomized cross-over study (see Figure). Two non-overlapping alternate forms (Form A (FA)) and Form B (FB)) with eight unique items each from three of the PROMIS domains (emotional distress-depression, fatigue, physical function) will be developed. Respondents will answer one of the forms by automated phone interview using interactive voice response (IVR) technology, paper and pencil questionnaire (PP), personal computer (PC), or personal digital assistant (PDA) technology. The other form will always be answered by PC. The order in which the forms are administered will be randomized. The two assessments will be separated by a short interval (e.g., 5-10 minutes), but will take place on the same day. The study is powered to evaluate equivalence within a score difference of +/-2.0 on a T-score metric (standard deviation of 10) with 85% power. Data for the IVR-PC, PP-PC and PC-PC modes will be collected via Polimetrix (n=200 per arm, with random assignment to arm); data for the PDA-PC mode will be collected via Stony Brook (n=200). Respondents will have one or more of the chronic conditions studied in other Wave 2 studies (COPD, depression, or rheumatoid arthritis).

**Figure: Study Design Schema**



**Overall Recruitment Status**

Not yet recruiting

**Study Start Date:**

Anticipated 11/2008

**Study Completion Date:**

Anticipated 05/2009

**Study Design:  
(Observational Study Model)**

Other. This is a randomized intervention study using a cross-over design. The "intervention" is the different modes of data collection.

**Time Perspective:**

Cross-sectional

**Enrollment:**

Target: 800

**Number of Groups/Cohorts:**

200 people in each of 4 groups: (IVR-PC, paper/pencil-PC, PDA-PC, PC-PC)

**Primary and Secondary Outcome Measures**

Primary Outcome Measures: IRT-derived scores from two parallel static short forms containing eight items each from three PROMIS domains (emotional distress-depression, fatigue, physical function)

**Primary Outcome Measure:**

Outcome Measure: Emotional distress-depression, fatigue, and physical function

**Secondary Outcome Measure:**

Time Frame: One-time assessment

Outcome Measure: Respondent preference and satisfaction

Time Frame: One-time assessment

<b>Group/Cohort Label:</b>	IVR-PC, PP-PC, PC-PC, and PDA-PC.
<b>Group/Cohort Description:</b>	The study groups differ in terms of modes of data capture.
<b>Intervention Type:</b>	Other: The intervention is mode of survey administration.
<b>Conditions or Focus of Study:</b>	Differences in modes of data capture will be evaluated with patients who have chronic obstructive pulmonary disease, depression, or rheumatoid arthritis.
<b>Keywords:</b>	Mode of administration
<b>Study Population Description:</b>	Community samples with at least one of these conditions: chronic obstructive pulmonary disease (COPD), depression (DEP), or rheumatoid arthritis (RA).
<b>Sampling Method:</b>	Non-Probability Sample
<b>Eligibility Criteria:</b>	<p>Inclusion criteria:</p> <ol style="list-style-type: none"> <li>1. Diagnosis given by treating physician.</li> <li>2. Respondents required to take one or more of the following medications for their treatment.</li> </ol> <p>COPD: Inhalative steroids (e.g., budesonid, beclometason), oral medication with theophylline (dimethylxantine), 2 mimetica (e.g., formoterol, salmeterol), leukotrien antagonists (e.g., montelukast), or oral corticosteroids (e.g., prednisolone).</p> <p>DEP: Anti-depressive drugs (e.g., mitrazapine, escitalopram) and/or received a recognized psychotherapeutic treatment for depression within the last year.</p> <p>RA: Anti-inflammatory medications (e.g., Cox-2 inhibitors, acetylsalicylic acid &gt;500mg/d, diclofenac, ibuprofen), immunosuppressants (e.g., methotrexate, lefunomide), immune modulators (e.g., infliximab, etanercept), or steroids (e.g., prednisolone) for current treatment of RA.</p> <ol style="list-style-type: none"> <li>3. Age 18 or older</li> <li>4. Fluent in English</li> <li>5. Have Internet access and an e-mail address (for the IVR-PC, PP-PC and PC-PC arms)</li> <li>6. Willing and able to give informed consent</li> </ol> <p>Exclusion criteria: None</p>
<b>Gender:</b>	Both
<b>Age Limits:</b>	<p>Minimum age: 18 years</p> <p>Maximum age: N/A</p>

**Facility:** IVR-PC, PP-PC, PC-PC arms: Internet data collection through Polimetrix, Palo Alto, CA, USA  
PDA-PC arm: Rheumatology Associates of Long Island, NY, USA

**Recruitment Status:** Not yet recruiting

**Facility Contact:**

**Investigators:** John E. Ware, Jr., Ph.D., Principal Investigator  
Arthur Stone, Ph.D., Co-Principal Investigator

**Central Contact:** Barbara L. Gandek, MS  
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