

# SUMMARY OF PROMIS WAVE 2 PROTOCOLS

## Mode of Administration Protocol Summary Information

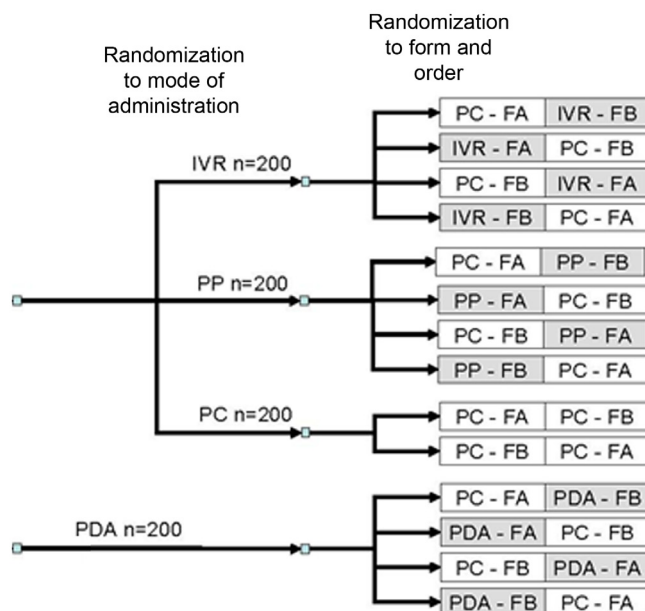
<b>Organization's Unique Protocol ID:</b>	07-05
<b>Brief Title:</b>	Impact of Mode of Administration
<b>Official Title:</b>	Investigating the Impact of Mode of Administration on Item Response
<b>Study Type:</b>	Observational
<b>Human Subjects Review:</b>	Submitted, pending
<b>Board approval number:</b>	N/A
<b>Board Name:</b>	New England Institutional Review Board
<b>Board Affiliation:</b>	New England Institutional Review Board
<b>Board Contact:</b>	Erin Brower, MS, CIP Director of Operations New England IRB 781-431-7577 40 Washington Street, Suite 130 Wellesley, MA 02481
<b>Oversight Authorities:</b>	United States: Institutional Review Board
<b>Sponsor:</b>	National Institutes of Health, National Institute of Arthritis and Musculoskeletal and Skin Diseases
<b>Collaborators:</b>	QualityMetric Incorporated, Stony Brook University, NorthShore University HealthSystem, Stanford University
<b>Brief Summary:</b>	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**



<b>Overall Recruitment Status:</b>	Not yet recruiting
<b>Study Start Date:</b>	Anticipated 11/2008
<b>Study Completion Date:</b>	Anticipated 05/2009
<b>Study Design: (Observational Study Model)</b>	Other. This is a randomized intervention study using a cross-over design. The “intervention” is the different modes of data collection.
<b>Time Perspective:</b>	Cross-sectional
<b>Enrollment:</b>	Target: 800
<b>Number of Groups/Cohorts:</b>	200 people in each of 4 groups: (IVR-PC, paper/pencil-PC, PDA-PC, PC-PC)
<b>Primary and Secondary Outcome Measures</b>	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)
<b>Primary Outcome Measure:</b>	Outcome Measure: Emotional distress-depression, fatigue, and physical function Time Frame: One-time assessment
<b>Secondary Outcome Measure:</b>	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>	Inclusion criteria: 1. Diagnosis given by treating physician. 2. Respondents required to take one or more of the following medications for their treatment. 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).

DEP: Anti-depressive drugs (e.g., mitrazapine, escitalopram) and/or received a recognized psychotherapeutic treatment for depression within the last year.

RA: Anti-inflammatory medications (e.g., Cox-2 inhibitors, acetylsalicylic acid >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.

3. Age 18 or older
4. Fluent in English
5. Have Internet access and an e-mail address (for the IVR-PC, PP-PC and PC-PC arms)
6. Willing and able to give informed consent

Exclusion criteria: None

**Gender:**

Both

**Age Limits:**

Minimum age: 18 years  
Maximum age: N/A

**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

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