

## 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

**Facility:** Stanford University School of Medicine  
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650-725-4612

**Recruitment Status:** Enrolling by invitation

**Facility Contact:** Karen Fisher, Research Process Manager  
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**Investigators:** James F. Fries, MD  
Site Principal Investigator

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