



Patient-Reported Outcomes Measurement Information System  
*Dynamic Tools to Measure Health Outcomes From the Patient Perspective*

# *Outcomes Measurement Information System (PROMIS): An NIH Roadmap Initiative*

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*On behalf of the PROMIS network*



# What Is PROMIS?

- An NIH Roadmap Initiative: Re-Engineering the Clinical Research Enterprise
- **Goal:** To improve assessment of self-reported symptoms and other health-related quality of life domains across many chronic diseases
  - Core domains include pain, fatigue, emotional distress, physical function, and social well-being
- **Structure:** 25+ Million, 5-Year cooperative agreement between NIH and extramural investigators
  - Statistical coordinating center
  - 6 primary research and data collection sites



# Themes of the NIH Roadmap

- **New Pathways to Discovery**
- **Research Teams of the Future**
- **Re-engineering the Clinical Research Enterprise**
  - Implement new paradigms in how clinical research information is collected, used, and reported.
  - Incorporate advances in information technology, psychometrics, and qualitative, cognitive, and health survey research.
  - Develop new partnerships of research with organized patient communities, community-based health care providers, industry, and academic researchers.

# Broad Objectives of PROMIS

## RFA-RM-04-011

- Develop and test a large item bank measuring patient-reported outcomes (PROs)
- Create a computerized adaptive testing system that will allow for efficient, psychometrically robust assessment of patient-reported outcomes for a wide range of chronic disease outcome research
- Create a publicly available system that can be added to and modified periodically and that will allow clinical researchers access to a common item repository and to computerized adaptive testing



# PROMIS Grantees

**David Cella, Ph.D.**  
**Northwestern U.**

**Westat**

**Medtap**

**UCLA**

**Dagmar Amtmann, Ph.D.**  
**U. of Washington**

**Jim Fries, M.D.**  
**Stanford University**

**Health Assessment Lab**

**Texas A & M**

**Darren DeWalt, Ph.D.**  
**U. of North Carolina**

**Scott & White Mem Hosp**

**Paul Pilkonis, Ph.D.**  
**U. of Pittsburgh**

**Assessment Systems**

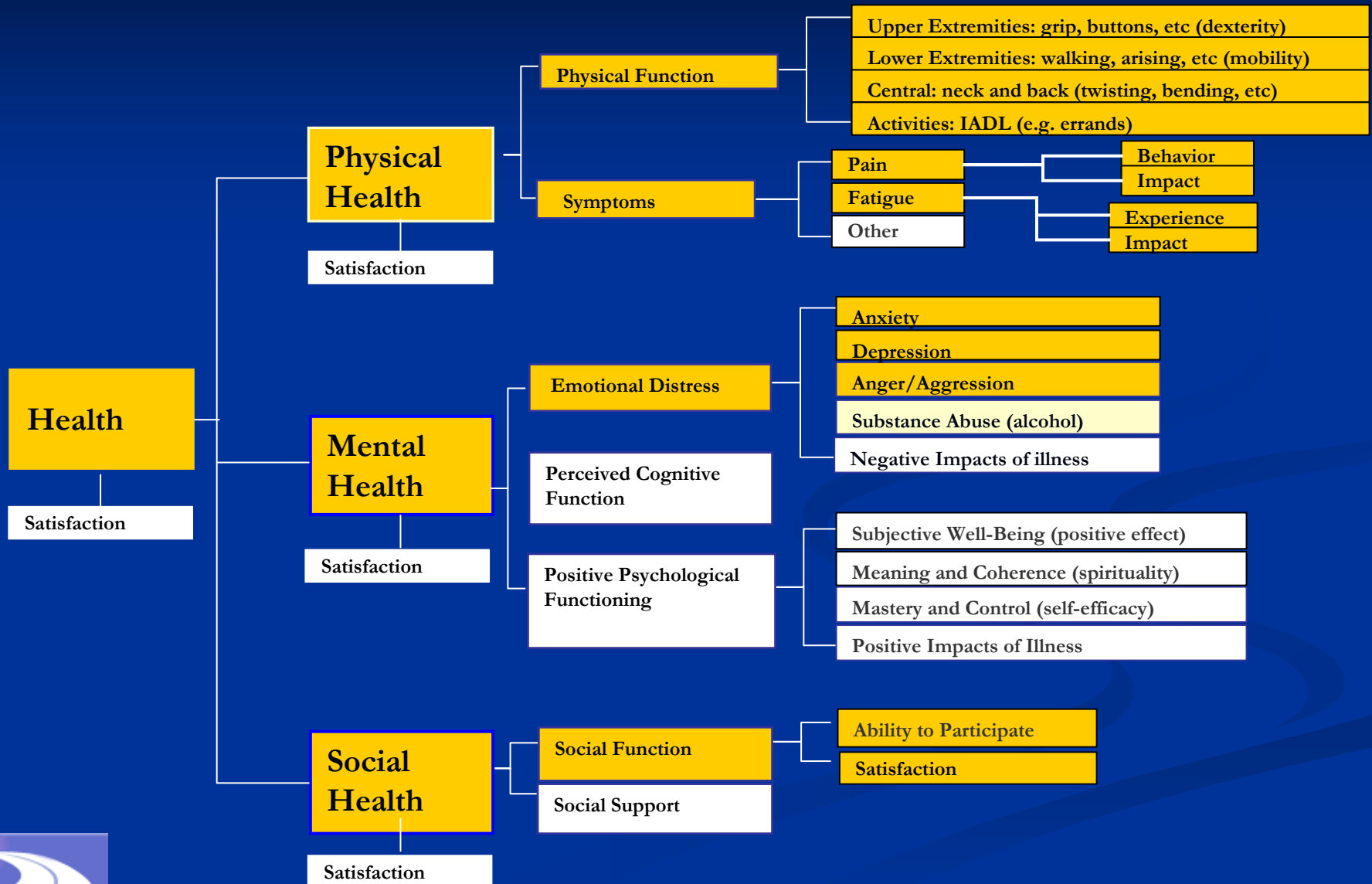
**Boston U.**

**Arthur Stone, Ph.D.**  
**Stony Brook University**

**U. of Michigan**

**Kevin Weinfurt, Ph.D.**  
**Duke University**

# PROMIS Domain Framework



# PROMIS Integrates Cognitive, Qualitative, and Survey Research Methods

- Conceptualize and operationalize the domains and issues affecting patients
- Build PRO assessment tools that are applicable for a broad range of respondents of various races, cultures, ages, education level, disease groups, and disease severity.
- Ensure content valid and meaningful results for researchers, clinicians, and patients



# What is a Computerized Adaptive Testing (CAT)?

- CAT integrates the advances in measurement theory and the power of computer technology to administer a PRO instrument that selects questions on the basis of a patient's response to previously administered questions.
- Highly informative questions are carefully selected so that we may determine a person's standing on a domain (e.g., physical functioning, depression) with the minimal number of questions without a loss in measurement precision.

# The “Promise” of PROMIS: Developing Instruments for Use in Clinical Research and Practice that:

- Reduce response burden.
- Improve measurement precision.
- Provide the ability to compare or combine results from multiple studies.
- Simplify administration via computer-based administration, scoring, and reporting.



# PROMIS Item Bank Development

- Extant review of existing items (legacy items)
- Development of new and modified items (approx. 8000 total new and derived items)
- Binning and winnowing of items (1064 items)
- Revisions for readability, consistency, and translation
- Patient focus groups
- Cognitive interviews (784 items)

Items from Instrument A

Items from Instrument B

Items from Instrument C

New Items

Item Pool

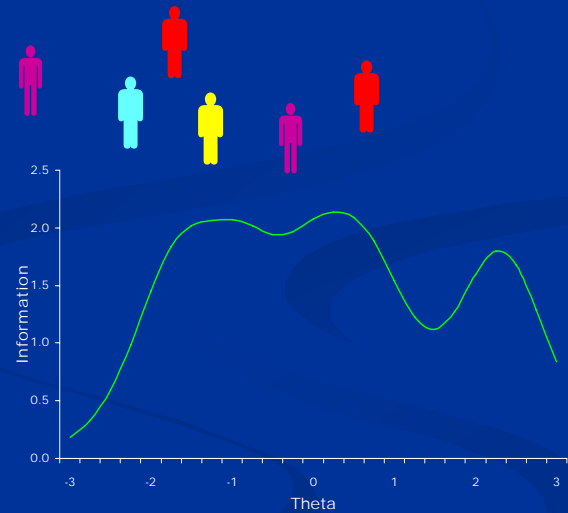
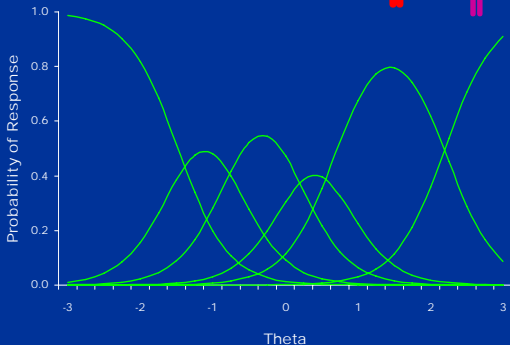
Content Expert Review

Focus Groups

Cognitive Testing

Secondary Data Analysis

Questionnaire administered to large representative sample



Psychometric Testing

Item Bank  
(IRT-calibrated items reviewed for reliability, validity, and sensitivity)

Short Form Instruments



# Additional Domain Development

## ■ Independent and Supplement Project Domains

- Pediatric Core Domains (Physical, Emotional, Social, School/Cognitive)
- Pediatric Asthma
- Sleep/Wake Functioning
- Sexual Functioning
- Perceived Cognitive Functioning

## ■ Supplementary projects

- Modified item banks for patients using wheelchairs and assistive devices
- Parent-proxy item banks that parallel the pediatric item banks
- Validation studies in patients with COPD, CHF

## ■ Collaborations with Other Federally Funded Initiatives

- DBDR/NHLBI AscQ-me project
- NCI PROMIS supplement (Cancer-relevant domains)
- NINDS NeuroQOL
- NIH Toolbox (Sensory, Motor, Cognitive, Emotional)
- CMS Post-Acute Care Demonstration Project

## Collaborations with Test Developers and End Users



# PROMIS Independent Projects and PIs

- **Duke University**

- Kevin Weinfurt, PhD

*Challenges for Using IRT-Based Assessments in Multi-center Clinical Trials*

- **Univ. of North Carolina, Chapel Hill**

- Darren DeWalt, MD, MPH

*Pediatric Reported Outcomes Assessment Using CAT ("Kitty")*



# PROMIS Independent Projects and PIs

- **University of Pittsburgh**

- Paul A. Pilkonis, PhD

*Measuring Patient-Reported Sleep and Emotional Distress*

- **Stanford University**

- James F. Fries, MD

*Improved Outcome Assessment in Arthritis and Aging*



# PROMIS Independent Projects and PIs

## ■ Stony Brook University

- Arthur A. Stone, PhD

*Ecological Validity in Patient-Reported Chronic Disease Outcomes*

## ■ University of Washington

- Dagmar Amtmann, PhD

*Improving Measurement of Pain and Fatigue and Increasing the Scientific Understanding of Pain and Fatigue in Children and Adults with Disabilities*



# Disease-Specific Validation Efforts

- Current PROMIS Network Validation Projects
  - Construct Validity and Sensitivity to Change in:
    - COPD
    - Depression
    - Back Pain
    - Congestive Heart Failure
    - Arthritis
  - Mode of Administration Testing
- PROMIS item banks released specifically to encourage others to validate in their patient populations

# Collaborations

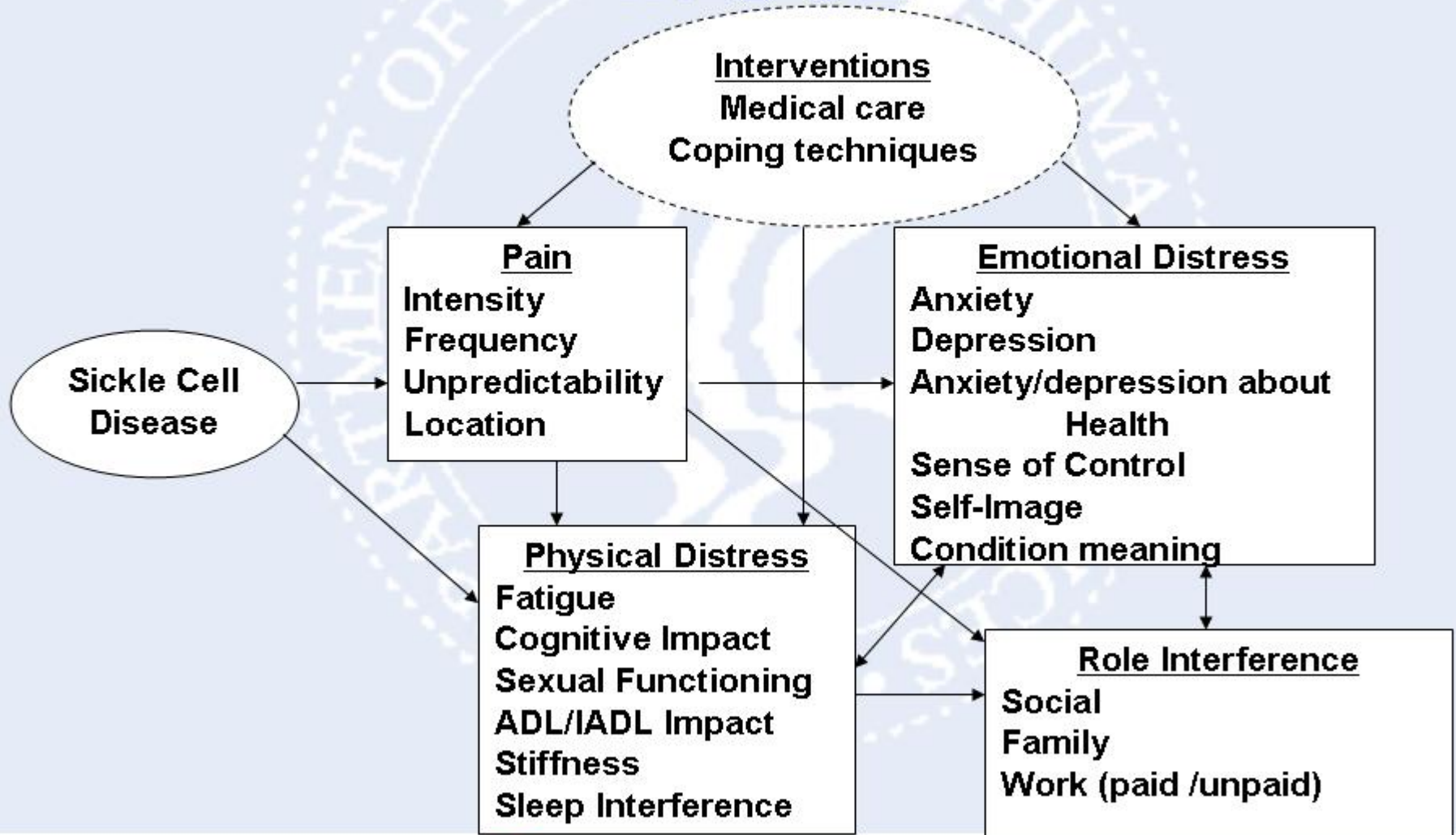
- Currently, there are 114 collaborative projects
  - Translation & validation studies in non-US populations (Brazil, China)
  - Use of PROMIS measures in different clinical care settings (Cleveland Clinic, hospices & palliative care)
  - Development & use of PROMIS tools in a range of diseases & conditions
    - NCI PROMIS supplement (Cancer-relevant domains)
    - NINDS NeuroQOL
    - NIH Toolbox (Sensory, Motor, Cognitive, Emotional)
    - NHLBI ASCQ-me project (Sickle Cell Disease)



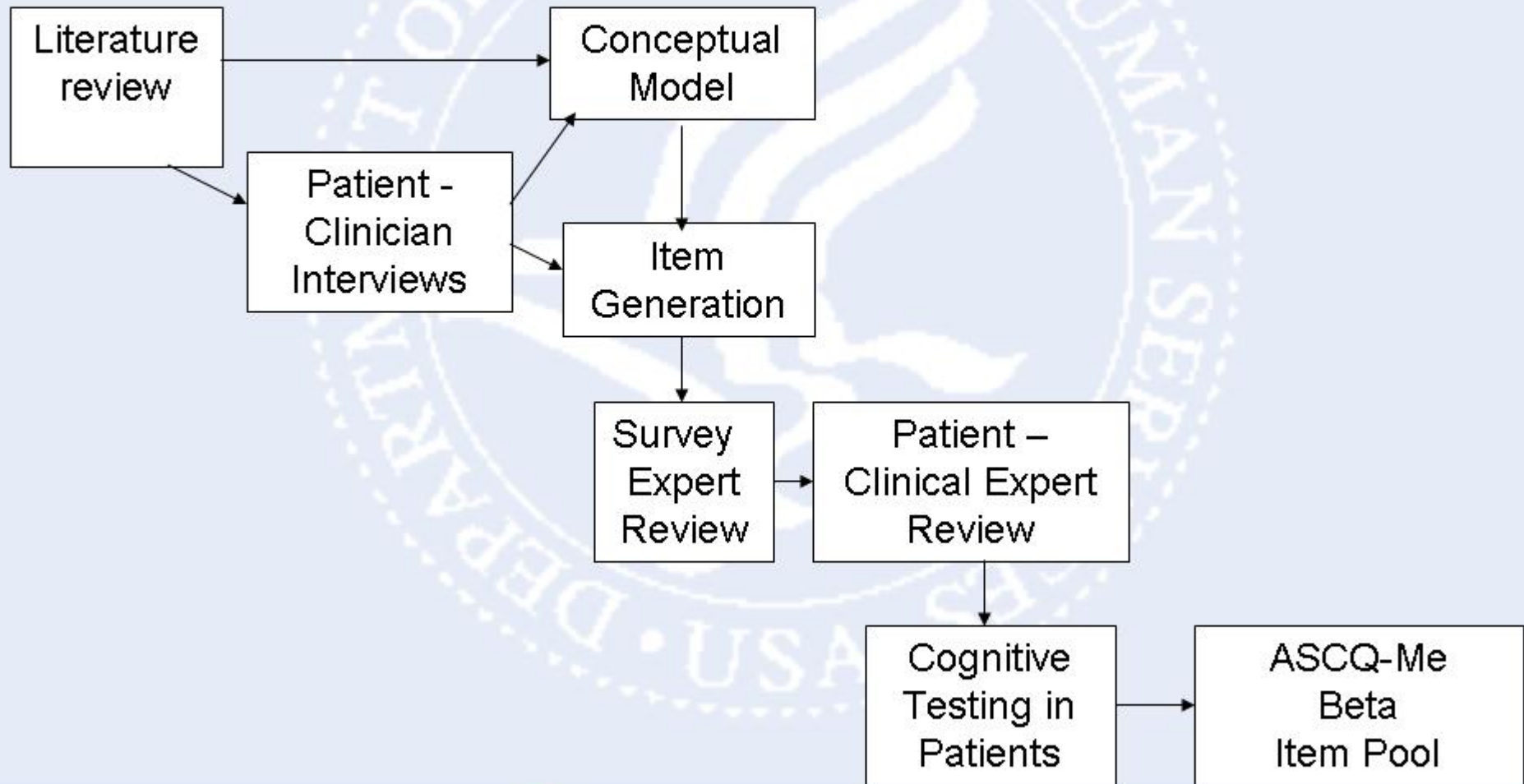
# Adult Sickle Cell Quality of Life Measurement Information System (ASCQ-Me)

- **Primary Purpose:** To develop, validate, and disseminate a health-related quality of life (HRQOL) measurement information system for Sickle Cell Disease (SCD) patients
- **Secondary Purpose:** To identify core data elements for a short form to be used as a paper-and-pencil questionnaire

# Conceptual Model for HRQOL in SCD



# ASCQ-Me Conceptual Model & Item Generation



# PROMIS II

- NIH Roadmap committed to an additional network funding through 2013
- PROMIS II to begin August 2009
- PROMIS II goals include:
  - Development and testing of additional item banks
  - Further validation of existing and new domains
  - Further improvements to Assessment Center
  - Development of a public-private partnership to sustain PROMIS post Roadmap funding.



# The PROMIS Potential

- Standardize the measures used in clinical research to enhance our ability to evaluate the effectiveness of interventions and treatments in clinical research and trials
- The ability to link databases (e.g., EMR) with systems like PROMIS would strengthen our national capacity to monitor progress against the burden of disease and to support a wide range of studies on the determinants of health care utilization and outcomes\*.

\*Source: Lipscomb J., Donaldson M.S., Hiatt R.A. Cancer outcomes research and the arenas of application. *JNCI Monographs*; 33, 2004, 1-7.



# WEBSITES

PROMIS: [www.nihPROMIS.org](http://www.nihPROMIS.org)

Roadmap: [www.nihroadmap.nih.gov](http://www.nihroadmap.nih.gov)

