The Origins and Promise of PROMIS –
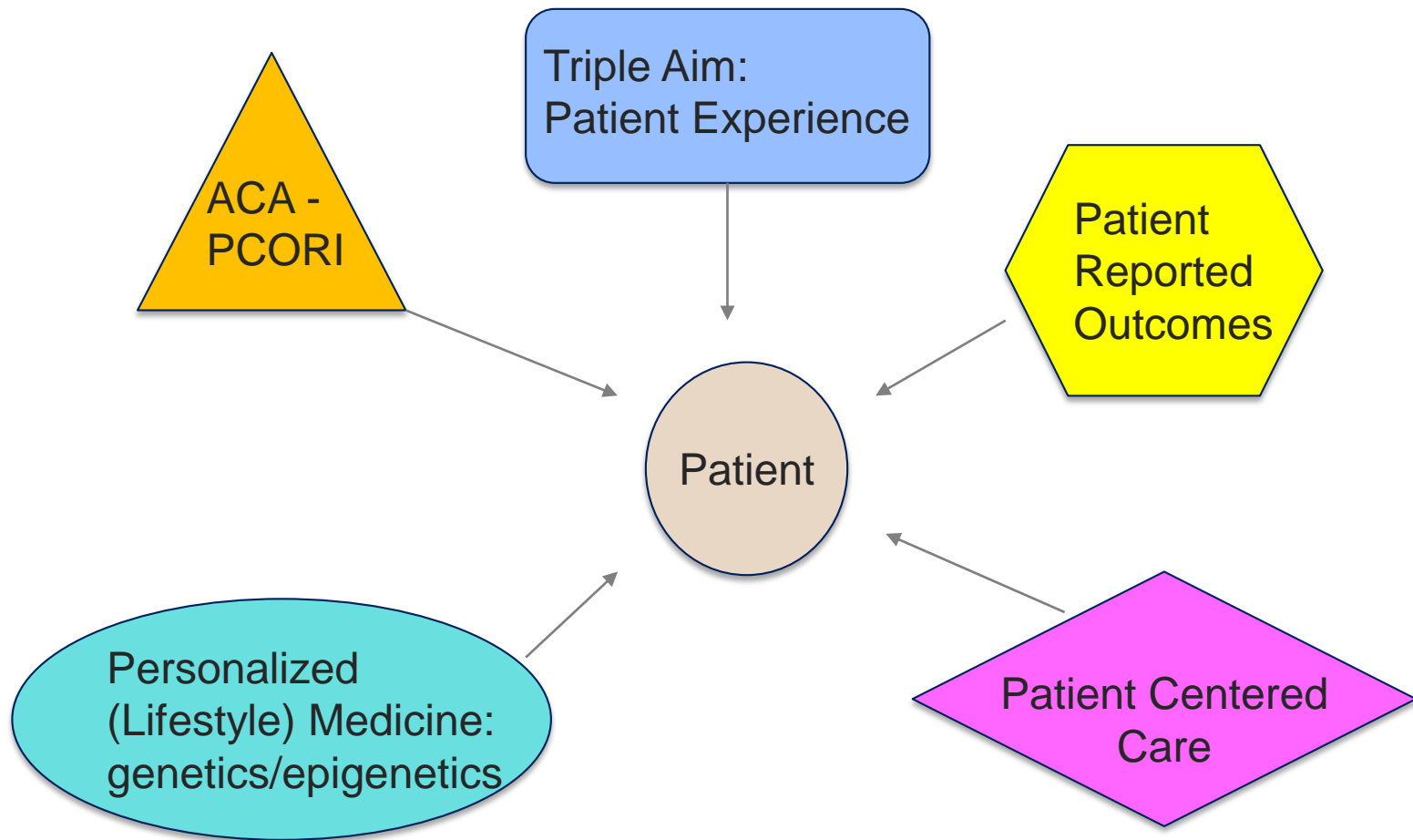## Patient Reported Outcomes Measurement Information System

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	Selected Milestones in Health Care Interventions and Delivery Strategies and in Research Methods.*	
Decade	**Milestones in Health Care Interventions and Delivery Strategies**	**Milestones in Research Methods**
1940s	Antibiotic agents (penicillin and streptomycin), kidney dialysis, general anesthesia, radiotherapy, first heart-pump machine, influenza vaccine, Papanicolaou (Pap) smear to detect cervical cancer, cortisone, intraocular lens implants for cataracts	First large-scale, randomized, controlled trial
1950s	Cardiopulmonary resuscitation, kidney transplantation, vaccination against poliomyelitis, chlorpromazine for schizophrenia, Zeiss fluorescence micro-scope, antitubercular therapy, cardiac pacemaker, artificial heart valve, successful open-heart bypass surgery	Case–control methodology, Kaplan–Meier survival estimator
1960s	Charnley's hip replacement, coronary-artery bypass grafting surgery, heart trans-plantation, oral contraceptive pill, prenatal diagnosis of Down's syndrome	Explanatory versus pragmatic trial concept, data and safety monitoring, growth of observational research methods committees
1970s	Cure for some childhood cancers; neonatal intensive care; computed tomography; coronary angiography; quality measures in health care; ambulatory surgery; vaccinations against smallpox, measles, mumps, rubella, and pneumonia	Cox proportional-hazards model; meta-analysis; ascendancy of randomized, controlled trials; statistical stopping rules
1980s	Insulin therapies for diabetes mellitus, thrombolysis for heart attacks, anti-hypertensive drugs, magnetic resonance imaging, robotic surgery, perma-nent artificial-heart implant, deep-brain electrical stimulation system, first laser surgery on the human cornea, hepatitis B vaccine	Propensity score; large, simple trials; prognostic models (e.g., Framingham risk score), growth of decision and cost-effectiveness analyses
1990s	Coronary stents, triple therapy for the acquired immune deficiency syndrome, introduction of biologics, "physician extenders," facial transplantation, vaccine against hepatitis A, first rotavirus vaccines	Evidence-based medicine, cumulative meta-analy-sis, reporting guidelines (CONSORT statement), ascendancy of registries, electronic health rec-ords, Markov chain Monte Carlo sampling for Bayesian inference
2000s	Human Genome Project completed, drug-eluting coronary stents, FDA guid-ance on patient-reported outcomes, minimally invasive techniques for surgery, human papillomavirus vaccine to prevent cervical cancer	Trial registration (ClinicalTrials.gov), comparative-effectiveness research, implementation science, large-scale genomic research, reproducible research
2010s	Genomics, epigenomics, individualized medicine, health information tech-nology, emergence of telehealth, meaningful-use initiatives, Affordable Care Act becomes law	Patient-centered outcomes research

* Information on health care interventions and delivery strategies are from Le Fanu.[1] CONSORT denotes Consolidated Standards of Reporting Trials, and FDA Food and Drug Administration.

History of PROMIS

- 2002 - NIH Roadmap for Medical Research in the 21st Century: goals were to improve the translation of new scientific discovery into tangible benefits for people; and propose a more efficient and productive system of research; three areas:
  - New Pathways of Discovery – better toolbox; wider access
  - Research Teams of the Future – new partnerships; high risk/payoff
  - Re-engineering the Clinical Research Enterprise – more systematic infrastructure to accelerate and strengthen process

- 2004 – NIH multi-center cooperative group- PROMIS (Patient Reported Outcomes Measurement Information System)
  - 6 primary research sites (PRS)
  - Statistical Coordinating Center (SCC)
  - Steering Committee (SC), Scientific Advisory Board (SAB) and Advisory Panel on Health Outcomes (APHO)

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PROMIS Goals

- Build and validate common accessible item banks for measuring key symptoms and health status domains across a range of chronic conditions
- Use of Item Response Theory (IRT) methods to assess available items or those developed; develop "computerized adaptive testing" (CAT) allowing individualized application of surveys
- Stimulate and standardize clinical trials across topics and NIH agencies that deal with patient-reported outcomes (PROs)
- Improve health status measurement in chronic conditions
- Help individual clinicians measure patient responses to interventions and design subsequent modification of treatment plans

Initial Work – first 2 years

- Developed 3 initial key protocols:
  - <u>Domain Mapping</u> – preliminary PROMIS framework rests on WHO physical, mental and social framework; subsequent iterative process led to current listing of domains and subdomains
  - <u>Archival Data Analysis</u> – reviewed large datasets with PROs and subjected them to IRT analysis to inform ultimate item choices then presented to domain working groups
  - <u>Qualitative Item Review (QIR)</u> – further review of items selected
- Developed the PROMIS Item Library – extensive database of PROs
  - 10,000 items (7K of which related to initial 5 subdomains)
  - "binning and winnowing"; characteristics: context/stem/response options/time frame/origin
  - Focus groups across diseases to check framework; patient groups to check cognitive qualities (e.g. clarity, readability)
- Chose 5 subdomains for item bank construction:
  - physical functioning, fatigue, pain, emotional distress and social role participation

# Domain Groups Drive Process of Item Development

- Domain groups – combine domain-specific content expertise with input from archival data to create initial item pools

- SCC coordinates initial input from domain content experts, domain mappers, PRS psychometricians, qualitative reviewers

- Iterative 6-step process with additional analyses produces the final set of items for field testing
  - identification of existing items, item classification and selection, item review and revision, focus group input on domain coverage, cognitive interviews with individual items, and final revision before field testing

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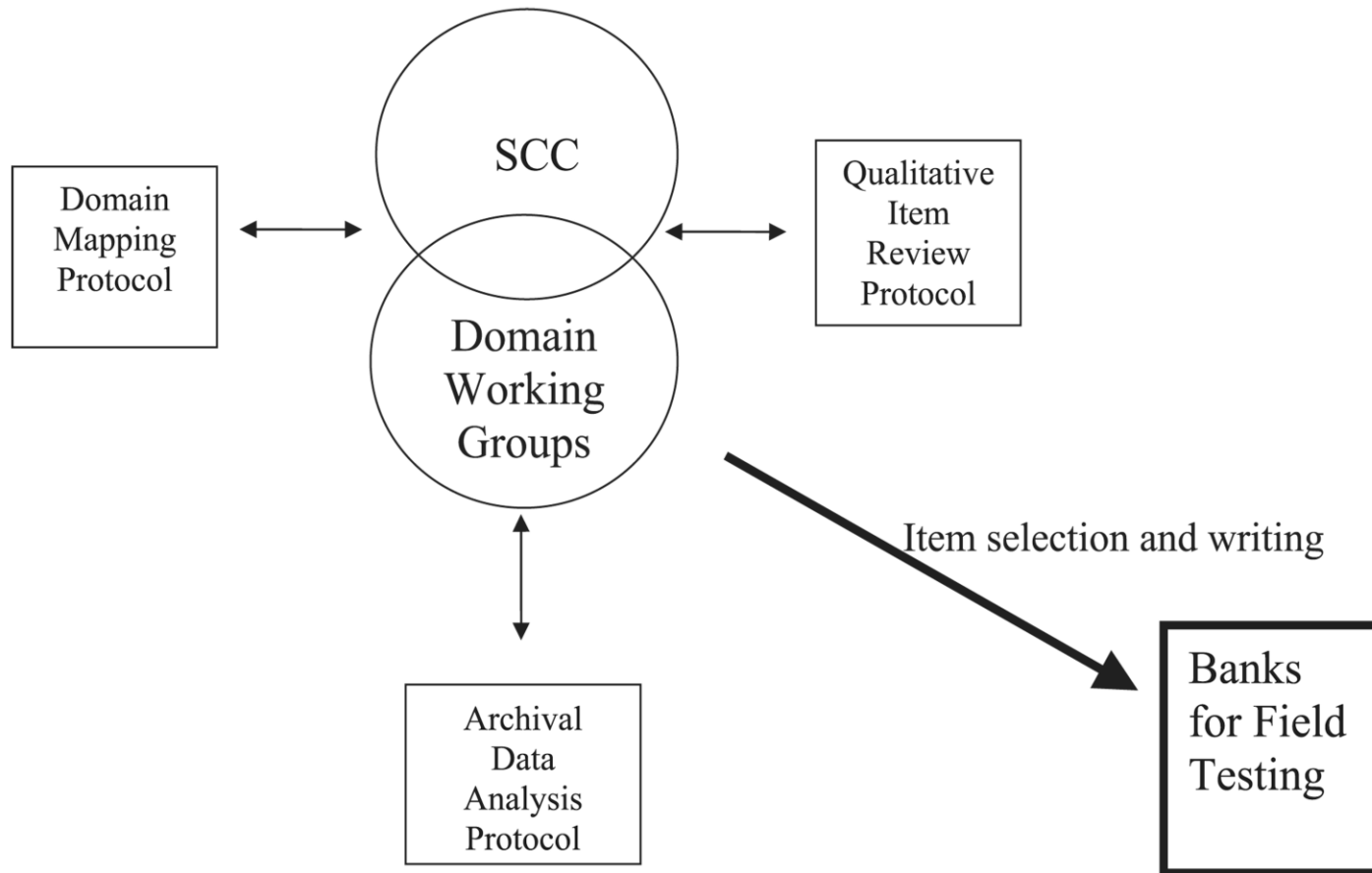
NOTE: SCC = Statistical Coordinating Center

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PROMIS Domain Framework
July 24, 2012
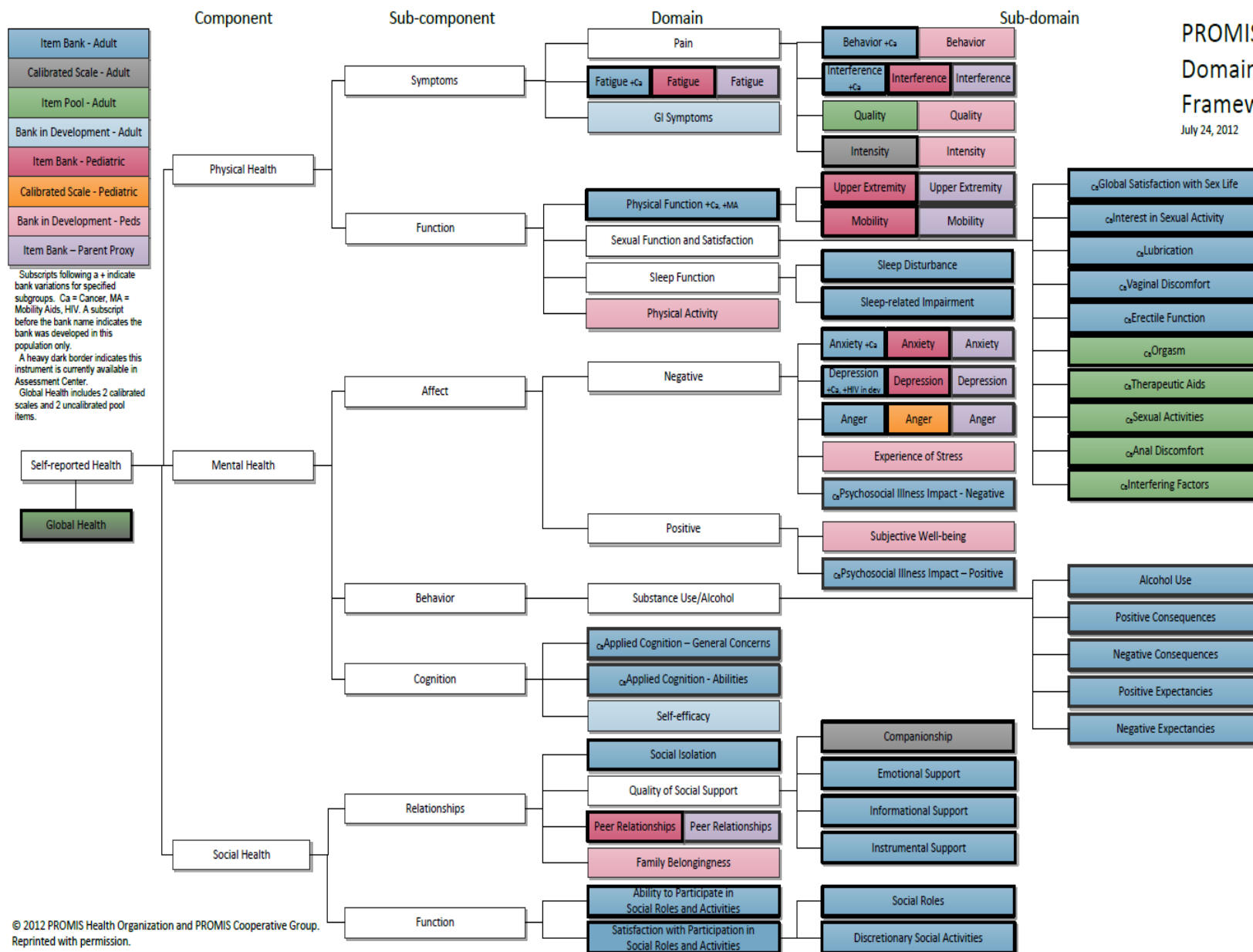
PROMIS Adult Self-Reported Health

Global Health

Physical Health | **Mental Health** | **Social Health**

PROMIS Profile Domains

Physical Health:
- Physical Function
- Pain Intensity
- Pain Interference
- Fatigue
- Sleep Disturbance

Mental Health:
- Depression
- Anxiety

Social Health:
- Ability to Participate in Social Roles & Activities

PROMIS Additional Domains

Physical Health:
- Pain Behavior
- Pain Quality
- Sleep-Related Impairment
- Sexual Function
- Gastro-Intestinal Symptoms
- Dyspnea

Mental Health:
- Anger
- Cognitive Function
- Alcohol Use, Consequences & Expectancies
- Smoking
- Substance Abuse
- Psychosocial Illness Impact
- Self-efficacy

Social Health:
- Family Belonging
- Family Involvement

3/30/2015

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The First 5 Subdomains

- **Physical Functioning** - physical ability to carry out activities of daily living to more vigorous activities
- **Fatigue** - overwhelming, debilitating, sustained sense of exhaustion that interferes with daily activities
- **Pain** - sensory and emotional
- **Emotional Distress**
  - Depression
  - Anxiety
  - Anger
- **Social Health**
  - Social function (involvement and satisfaction)
  - Social support (both quantitative and qualitative)

PLUS Global Health
  - Summaries of above 5
  - General health perceptions

Version 1.0 Item Banks - 2008

Domain	Item Bank # of Items	Short Form # of Items
Emotional Distress – Anger	29	8
Emotional Distress – Anxiety	29	7
Emotional Distress – Depression	28	8
Fatigue	95	7
Pain – Behavior	39	7
Pain – Impact	41	6
Physical Function	125	10
Satisfaction with Discretionary Social Activities	12	7
Satisfaction with Social Roles	14	7
Sleep Disturbance	27	8
Wake Disturbance	16	8
Global Health	—	10

Current Instruments Available

- Adult Short Forms   90
- Adult Item Banks   14
- Adult Profiles   6
- Global Health   1
- Pediatric Short Forms   9
- Pediatric Item Banks   8
- Pediatric Profiles   6
- Parent Proxy Item Banks   8
- Parent Proxy Short Forms   9

PLUS Spanish Language instruments

Global Health

Please respond to each item by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02	In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global09	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)...................	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Completely	Mostly	Moderately	A little	Not at all
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

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PROMIS v.1.1 - Global

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Global10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		None	Mild	Moderate	Severe	Very severe
Global08	How would you rate your fatigue on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		0 No pain	1	2	3	4	5	6	7	8	9	10 Worst imaginable pain
Global07	How would you rate your pain on average?...........	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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PROMIS–29 Profile v2.0

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
1	Are you able to do chores such as vacuuming or yard work?	☐	☐	☐	☐	☐
2	Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
3	Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
4	Are you able to run errands and shop?	☐	☐	☐	☐	☐

	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
5	I felt fearful	☐	☐	☐	☐	☐
6	I found it hard to focus on anything other than my anxiety	☐	☐	☐	☐	☐
7	My worries overwhelmed me	☐	☐	☐	☐	☐
8	I felt uneasy	☐	☐	☐	☐	☐

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Depression
In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
9	I felt worthless	☐	☐	☐	☐	☐
10	I felt helpless...	☐	☐	☐	☐	☐
11	I felt depressed..	☐	☐	☐	☐	☐
12	I felt hopeless..	☐	☐	☐	☐	☐

Fatigue
During the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
13	I feel fatigued	☐	☐	☐	☐	☐
14	I have trouble <u>starting</u> things because I am tired...	☐	☐	☐	☐	☐
15	How run-down did you feel on average? ...	☐	☐	☐	☐	☐
16	How fatigued were you on average?	☐	☐	☐	☐	☐

Sleep Disturbance
In the past 7 days…

		Very poor	Poor	Fair	Good	Very good
17	My sleep quality was...................................	☐	☐	☐	☐	☐

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing............................	☐	☐	☐	☐	☐
19	I had a problem with my sleep	☐	☐	☐	☐	☐
20	I had difficulty falling asleep	☐	☐	☐	☐	☐

Ability to Participate in Social Roles and Activities

		Never	Rarely	Sometimes	Usually	Always
21	I have trouble doing all of my regular leisure activities with others	☐	☐	☐	☐	☐
22	I have trouble doing all of the family activities that I want to do	☐	☐	☐	☐	☐
23	I have trouble doing all of my usual work (include work at home)	☐	☐	☐	☐	☐
24	I have trouble doing all of the activities with friends that I want to do	☐	☐	☐	☐	☐

Pain Interference
In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
25	How much did pain interfere with your day to day activities?	☐	☐	☐	☐	☐
26	How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
27	How much did pain interfere with your ability to participate in social activities? .	☐	☐	☐	☐	☐
28	How much did pain interfere with your household chores?	☐	☐	☐	☐	☐

Pain Intensity
In the past 7 days…

29	How would you rate your pain on average?...	☐ 0 No pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Worst imaginable pain

What Is the Assessment Center?

- Assessment Center is a free, online research management tool. It enables researchers to create study-specific websites for capturing participant data securely. Studies can include measures within the Assessment Center library as well as custom instruments created or entered by the researcher. PROMIS instruments (short forms, CATs, profiles) are a central feature of the instrument library within Assessment Center. Any PROMIS measure can be downloaded for administration on paper or be included in an online study. Detailed statistical information and development history about PROMIS items and instruments is available for review.

- Assessment Center enables customization of item or instruments (e.g., format, randomization, skip patterns), real-time scoring of CATs, storage of protected health information in a separate, secure database, automated accrual reports, real-time data export, graphing of individual PROMIS CAT or Profile scores, and ability to capture endorsement of online consent forms among many other features.

From AssessmentCenter_Manual.pdf

PROMIS Resources/References

- Assessment Center:
  - http://www.assessmentcenter.net/
- Assessment Center User Manual:
  - http://www.assessmentcenter.net/ac1/AssessmentCenter_Manual.pdf
- CAT demonstration:
  - https://www.assessmentcenter.net/ac1/Default.aspx?SID=DD7EBF2C-7F6D-4FFD-9953-94CBEA8169D3
- Publications:
  - http://www.nihpromis.org/science/publicationsyears
- Presentations:
  - http://www.nihpromis.org/science/presentations
- References:
  - Med Care. 2007 May ; 45(5 Suppl 1): S3–S11.
  - *J Clin Epidemiol*. 2010 November ; 63(11): 1179–1194.
  - The Patient Reported Outcomes Measurement Information System (PROMIS): A Walk Through the First Four Years. PROMIS website.