

**Patient Reported Outcomes Measurement Information System
(PROMIS) Network Study Protocol**

Patient Reported Outcomes Measurement
Information System (PROMIS) Network Study
Protocol (QIR)

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I. Introduction

The qualitative item review (QIR) process begins once classification of items (“binning”) and selection of items for further review (“winnowing”) for a given domain’s potential item bank is complete. A detailed description of binning and winnowing can be found in the Domain Hierarchy protocol. QIR will consist of three efforts: (1) expert item review (EIR), (2) focus groups, and (3) cognitive interviewing. Although quantitative information will also be used in conjunction with these qualitative endeavors to help determine the form and content of final item banks for each domain, these three efforts represent qualitative approaches to improving and adapting items for administration in a computer-based testing (CBT), computer adaptive testing (CAT) and item-response theory (IRT) framework for PROMIS.

II. Rationale and Objectives

Prior to QIR, PROMIS activities have included review of the literature and existing instruments, establishment of conceptual frameworks for each domain, and amassing of items in banks that at that point contained many more potential items than would be possible to administer, in forms not yet ready for administration. Binning and winnowing of the items prior to QIR will have ensured relevance to the domain frameworks, and organized and streamlined the item banks by categorizing and paring down the massive quantities of items in each bank. QIR will prepare the items for administration by further categorizing, unifying, and re-writing them to produce a set of items that are relevant, optimized, and adapted to the technologies we plan to use (CBT, CAT and IRT). Similar to scale development processes, item preparation through QIR will create new items and adapt existing items based on two key sources: expert opinion (expert item review; EIR) and patients/potential research participants (the focus groups and cognitive interviews tasks). The focus groups will help provide patient input to conceptual gaps in the domain definition leading to the identification of new items, especially where it is judged that existing items do not provide adequate coverage. The cognitive interviews will help ensure that items can be understood with the intended interpretation by potential research participants, especially those with low literacy. Specific procedures for conducting focus groups and cognitive interviews will discuss these processes in detail. By incorporating existing methods of scale development into the preparation of the items, the QIR process is a critical part of how PROMIS will carry out the charge of developing and testing new technologies to measure patient-reported outcomes (PROs).

The three QIR tasks described in this protocol thus share the common objective of item refinement. The goals of item refinement are to end up with re-written and/or new items expected to be:

- comprehensive in measuring each subcategory of the domain
- clear and understandable
- precise (measures a single concept)
- acceptable to respondents
- amenable to linguistic translation
- adapted to the data collection and analysis strategies planned

III. QIR Tasks

Task	Assigned Network Members
A: Achieve consensus on response categories	PROMIS network members representing all domains
B: Review and revision of items	Two domain members working collaboratively
C: Review of revised items	One network member (inside or outside of domain)
D: Reach consensus on all items' revisions	Three network members; translatability assessment by SCC or site personnel with translation expertise
E: Focus groups evaluate conceptual gaps in domain and domain framework	Patients from multiple disease groups
F: Construction of new items based on focus group feedback	Domain workgroup members
G: Cognitive assessment for each item	Patients from multiple disease groups
H: Revision of items based on cognitive assessment	Domain workgroup members
I: Assignment of surface characteristics	Domain workgroup members
J: Review of finalized items	Entire domain workgroup
K: Submission of items to Statistical Coordinating Center (SCC) in test-ready form	Domain chairs

IV. Section A: Expert Item Review

Instructions are provided on EIR procedures for use by the entire PROMIS Network. This includes responsibilities for conducting EIR, proposed tasks for conducting EIR, and criteria for evaluating items in preparation for the next phases of QIR (focus groups and cognitive interviewing).

A. Who Will Conduct EIR?

We propose that three people review each item for EIR. Two Workgroup members from each domain will work together to produce a set of re-written items. A third collaborator who is a network member inside or outside of the domain will then participate in the process as described below. The same three people will not necessarily review all items; rather, several teams may be formed. The entire Domain Workgroup will be involved in the last phase of reaching consensus on all items. The final set will be submitted to those PROMIS members who are conducting focus groups and cognitive interviews for further refinement as part of the remaining QIR efforts.

B. Proposed QIR Logistics

Based on review of the literature and the binning/winning processes associated with the Domain Hierarchy protocol, each domain group will submit a list of proposed response categories for the PROMIS network. Using a modified Delphi approach, these suggestions will be reviewed by the Steering Committee and modified. Translation experts at the SCC will be consulted to provide feedback about the translatability of each response set. An initial set of response categories will be proposed to be utilized during EIR item revision [QIR Task A]. These response categories may change further based on results of archival data analyses and initial testing. See Appendix A1 for the initial preferred response categories.

Individual item review and revision will then commence. A proposed model for the initial 2-person collaboration is for the two domain members to meet or speak to categorize and suggest re-written forms of a portion of the items, aiming to reach consensus on that portion. For the rest of the items, the 2 domain members may find it useful to set up times to continue to work together, or they may choose to work

separately, reconvene, and reach consensus. At the end of the first meeting, the 2 members should plan for further communication and strategy for covering the rest of the items. Two domain members will review and revise as needed all items within their domain [QIR Task B].

Once a set of items has been reviewed and re-written (if necessary) the 2 domain members will submit the items to a third collaborator for review. This third collaborator will (a) sign off on items that appear to need no further revision, indicating consensus, and (b) suggest revisions to items that may still be improved [QIR Task C]. The third reviewer will then collaborate with 2 domain group members to reach consensus on the final re-written form of each item [QIR Task D]. A final list of items will be sent to translation experts at the SCC who will provide feedback about the translatability and cultural relevance of the proposed items, and will work with the domain group to revise items as needed to improve translatability and cultural relevance. This review can be done at the PRS if translation experts are available on site. Focus groups will be conducted to review the domain definition and Domain Hierarchy to identify conceptual gaps [QIR Task E]. This input will be used by the domain workgroup to construct new items [QIR Task F]. All items will then be subjected to review by patients through cognitive interviews [QIR Task G]. Responses from these interviews will be used by the domain workgroup members to further revise items [QIR Task H]. Domain group members will review items and assign surface characteristic ratings [QIR Task I]. The entire Domain Workgroup will then review the final set of items [QIR Task J]. The Domain Chair will submit the domain's items to the SCC in test-ready form after giving his or her final approval [QIR Task K].

C. Criteria for Evaluating Items

Because the items received by the EIR reviewers will have already undergone binning and winnowing, we do not anticipate excluding many items. Rather, the PROMIS network has assumed that most items will need at least some level of re-writing, ranging from minor tweaking to complete overhaul.

Items should be re-written with the goal of optimization. The principle here is to preserve as much as possible of the original item, but to help the item fit within the

PROMIS framework for administration. For confusing items, this process offers the opportunity for making them clearer.

D. Re-write Reasons

PROMIS will use the following guidelines for re-writing. The reason(s) for item revision will be documented. By documenting the reasons for rewriting the items, we will have an audit trail to describe any changes that were made from original items. The following are reasons for items to be revised.

Clarity: Items that are unclear will be revised to aim for (a) clarity of instructions to respondent, and (b) clarity of the item text, including singularity of concept. Consider revising if an item seems too long, written at a high literacy level, or is written with poor grammar. If an item appears too vague to elicit a concrete response, suggest revision. Consider revising any aspects of the item context, stem, or response options that would present significant challenges to translation and cross-cultural applicability. For example, the concept of walking a “block” may not be applicable to non-North American cultures.

Precision: If an item measures more than one concept, re-write to break down into one-item-per-concept. Also, if an item is ambiguous and can be interpreted in more than one way, it should be re-written so that the ambiguity is resolved.

Acceptability to respondents: Consider revising any aspects of the item context, stem, or response options that would impede one’s ability or willingness as a respondent to provide an informative answer.

Adaptation to data collection format (CBT and CAT)

Format of items: Items may be revised to meet PROMIS network format for item stems and contexts. The item stem is usually a standalone statement or question that captures the essence of what is to be measured. For example, "I have to limit my social activity because of my health"; "Has your health interfered with your social activities?" The item context is generally some instructional material, often including the timeframe. For example, "Please indicate how true each statement has been for you during the past 7 days." Since the ultimate goal is to create CAT where only one item shows on the screen at a time, and the order of items is selected by computer algorithm, EIR may incorporate some of the item context into the item stem itself in order to create a stand-alone item. Other aspects of item context (e.g., time frame, general directions, etc.) will be set aside

for future use according to PROMIS-wide conventions that will be developed, e.g., displaying it only once in an introductory screen, displaying it on every screen, etc. Attention will be paid to item length as well due to translations increasing item length by 30%.

Set of preferred response options: Items may be revised to fit a PROMIS network adopted response set. Most if not all items will utilize a network accepted response set. Response options may be adapted by domain workgroups.

Time frame: The PROMIS network has accepted a 7-day recall period for most, if not all, items. Items may need to be revised to meet this timeframe. This time frame was chosen because it is on the upper limits of ecological validity for specific events (especially for subjective symptoms), yet long enough to allow for enough events to occur. Additionally, many clinical trials look for response to therapy over a few weeks time, and a longer recall time would sabotage the ability to detect benefits.

E. Assignment of Surface Characteristics

As the last step of EIR, each item will be reviewed and rated on surface characteristics. This step will help in later analyses to look at performance against certain item characteristics. The item and its rating scale will be evaluated together to determine the characteristics. It is anticipated that no items should be rated as multi-barreled or confusing after the previous revision process. The criteria for surface characteristics are:

Characteristic	Check off
Intensity/difficulty	Yes/no
Frequency	Yes/no
Point recall vs. Interval recall	Point/Interval
Specific event or experience	Yes/no
Association between 2 or more experiences	Yes/no
Interference of one experience upon another	Yes/no
Contains multiple items (multi-barreled)	Yes/no
Confusing item	Yes/no

After completion of revision and documentation of surface characteristics, the items will be sent to the SCC for evaluation by the Lexile Analyzer. The Lexile Analyzer will score each item on readability. This will be added as a characteristic of the item. For Lexile Analysis, the entire context and stem will be analyzed together for an individual item. The item stem may also be analyzed alone. Because of the non-grammatical format of response options, they will not be analyzed for readability. Items scoring higher than 900L (roughly sixth-grade level) will be flagged as potentially difficult for poor readers.

V. Section B: Focus Groups

A. Protocol Synopsis

Parameters	Participants
Recruitment:	Male and female patients will be recruited by each participating PRS according to the method approved by that PRS IRB review. Possible recruitment methods include <i>print media (mail or posted in clinic, e-mail notification, internet posting, clinic or hospital databases)</i>
Number of Participants:	<i>Eighteen</i> focus groups will be conducted across the PROMIS network covering each of the five initial generic domains selected for initial bank testing. Each focus group will include 6-12 participants and a trained facilitator. The focus group composition is detailed in Table 1 below.
Inclusion Criteria:	<ol style="list-style-type: none">1. At least 18 years of age;2. Self-reported diagnosis of condition that defines membership in focus group3. Self-reported ability to speak and read English;4. Willing to provide signed informed consent
Exclusion Criteria:	Concurrent medical or psychiatric condition that, in the PRS investigator's opinion, may preclude participation in this study; or Cognitive or other impairment (e.g., visual) that would interfere with completing a self-administered questionnaire or participating in a group discussion.
Instruments:	<ul style="list-style-type: none">▪ Focus group discussion guide.▪ Sociodemographic questionnaire provided by the SCC.▪ Domain-specific questionnaires provided by the PROMIS Domain Groups.▪ Optional: Wide Range Achievement Test – Reading subtest
Administration of Instruments:	Groups will be conducted according to the assignments noted in Table 1. Signed informed consent will be obtained at the time of recruitment or when participants arrive at the interview location prior to the start of the focus group session. Participants will be compensated as dictated by local IRB submissions, for their time upon completion of the focus group session. Focus group sessions will be audiotaped/or digital voice recorded for subsequent transcription.
Analysis:	Qualitative content analysis will be used to evaluate the information gathered during the focus groups. Descriptive statistics will be used to characterize the demographics of the sample population, which will be performed by the PROMIS domain chair. The domain chair is responsible for coordinating and overseeing the summarization of all domain focus group data and forwarding a summary of the data to the SCC.

B. Table 1: PROMIS Network Focus Group Plan

Domain	PRS (F.G. site)	Sub-domain	Population
Emotional Distress (ED)	Pitt	Depression	Outpatient Psychiatric
	Pitt	Anger	Outpatient Psychiatric
	Pitt	Anxiety	Outpatient Psychiatric
	Pitt	Alcohol	Outpatient Psychiatric
	Duke	Depression	Mixed
	Duke	Anger	Mixed
	Duke	Anxiety	Mixed
	Duke	Alcohol	Mixed
Social Role Participation (SRP)	UNC	SRP	Mixed (Internal Medicine)
	UNC	SRP	Mixed (Internal Medicine)
	UNC	SRP	Mixed (Internal Medicine)
	Pitt	SRP	Outpatient Psychiatric
Fatigue (F)	UNC	F	Mixed (Internal Medicine)
	UNC	F	Mixed (Internal Medicine)
	UWash	F	Rehab
Pain (P)	UNC	P	Mixed (Internal Medicine)
	UWash	P	Rehab
	Stanford	P	Arthritis
Physical Function (PF)	Stanford	PF	Arthritis/Aging
	UWash	PF	Rehab

C. Background and Purpose

Focus groups are commonly-used to understand new phenomena as viewed by important target audiences, and to develop new items for standardized questionnaires (Sudman, Bradburn, & Schwarz, 1996). Focus groups generate qualitative data that provide insights into the attitudes, perceptions, and opinions of participants solicited through the open-ended question and answer protocol (Krueger, 1994). Focus groups can combine the distinct advantages of qualitative and quantitative methods into an integrated survey research methodology (Krueger, 1994; Schwarz & Sudman, 1996). Specifically, focus group interviews can help the researcher discover the vocabulary and the thinking patterns of the target group prior to the development of quantitative standardized items for survey questionnaires. Focus groups can also identify special problems that might emerge in the quantitative phase of instrument development, such as an illogical sequence of items that obfuscate the intent of the survey items or confuse the respondent.

The PROMIS network has committed to develop and validate item banks for the following five domains of health-related quality of life: pain, fatigue, physical functioning, emotional distress, and social role participation. The primary intent of the PROMIS network focus groups will be to identify conceptual gaps in the domain definitions in order to characterize areas for new item development in each domain and identify common language related to the domain. A secondary goal of these groups is to obtain input regarding the comprehensiveness of the initial five selected domains, as defined by the PROMIS Domain Framework group. It is clear from the current domain framework that these five domains do not comprehensively cover health related quality of life, and it is expected that participants will affirm that view. The focus of this component of each group is to determine which of the remaining domains in the framework – or perhaps other domains not named in the framework – are the most important to pursue after bank development in each of these initial five domains. This will inform future activity of the PROMIS effort.

D. Methods

1. Overview

Domain-specific focus groups will be conducted at individual primary research sites (PRSs) according to the plan in Table 1. The PROMIS Steering Committee has reviewed and approved the focus group plan for implementation by domain, PRS, sub-domain, and population. This protocol describes the standardized methodology that will be applied in all groups. Each domain group is responsible for specifying eligibility criteria for participants and may vary to some degree on participant compensation. The methodology for data summary and analysis will be similar across domain groups and will be domain-specific only to the extent necessary to accommodate domain-specific content.

2. Participants

a) Inclusion Criteria

All participants in each of the focus groups must meet the following criteria to be eligible for this study:

1. At least 18 years of age;
2. Self-reported diagnosis of condition(s) that define membership in focus group
3. Self-reported ability to speak and read English; and
4. Willing to provide signed informed consent;

The following characteristics of patients to be included in the focus group are recommended:

1. A spectrum of severity (impairment) for the condition (or domain) involved.
2. Range of ages reflective of the condition under study.
4. Representation of both genders [*unless gender-specific groups are dictated by domain issues*].
5. Diversity of races/ethnicities.

b) Exclusion Criteria

Participants meeting one or more of the following criteria are not eligible for the study:

Having any concurrent medical or psychiatric condition that, in the PRS investigator's opinion, may preclude participation in this study; or

Cognitive or other impairment (e.g., visual) that would interfere with completing a self-administered questionnaire and with participating in a group discussion.

3. Recruitment Procedures

Potential participants will be recruited by research staff at the PRS conducting the group, in accordance with local ethics board approved methods. Potential recruitment methods can include print media or flyer postings (see Appendix B1 for example); e-mail or internet postings (see Appendix B2 for example); mailed letters to targeted clinic populations, perhaps including a postage-paid response card (see Appendix B3 and B4 for examples); or direct in-clinic or telephone recruiting from patient lists or patient visits. It is the responsibility of the PRS to submit its recruitment plan to the SCC and the local IRB. In the case of recruitment through advertisement, all interested respondents will be screened by research staff with a standard screening form (Appendix B5) to confirm eligibility. In the case of mail recruitment, potential focus group participants drawn from a clinic's patient database would be mailed an introductory letter and postage-paid response card. The introductory letter should provide an overview as to the purpose and nature of the focus groups and ascertains the patient's interest in participating in the focus group sessions (Appendix B3). Patients who are interested in participating in the focus groups will return a pre-addressed, stamped response card to the investigator's office indicating that they are interested in participating (Appendix B4). The research staff at the clinic will complete a brief contact information form for each eligible patient and all eligible patient respondents are contacted to schedule the focus group sessions.

The goal is to have 6-12 participants for each focus group. Of the number of patients who provide verbal consent, about 90% are expected to actually participate. Therefore, 8-13 individuals should be scheduled for each group. Attempts to oversample from underrepresented gender, age and ethnic groups should be made to avoid a narrow demographic pool of participants. Participants who arrive more than 15 minutes late should generally be excused from participation to avoid disrupting the flow and progress

of the group. Exceptions to the general rule can be made by the facilitator based upon group climate. Payment of excused participants is encouraged. A focus group must contain at least 5 participants; if fewer than 5 present for a scheduled group, each person should be interviewed individually using the focus group questions and protocol. For data analysis, these individual interviews will be used to examine and verify consistency among the other groups; however, the data will not be analyzed as focus group data.

4. Conducting the Group

a) Overview

Focus groups will typically last from one and a half to two hours, with 6 to 12 participants discussing the topics under consideration (Sudman et al., 1996). Participants will be selected based on characteristics they have in common that relate to the topic of the focus group (Krueger, 1994). A trained facilitator will use a semi-structured interview protocol including open-ended questions to elicit group participation and discussion on a specific topic area. The moderator will facilitate the participants' answers, keeping the discussion on the topics under consideration, but will otherwise be nondirective, supportive, and non-evaluative. Focus group sessions will be audiotaped and transcribed and qualitative content analysis will subsequently be performed. Data will be transferred to the SCC.

b) Facilitator Training

All focus group facilitators will have received training on the principles involved in conducting focus groups. This training includes an overview of focus groups as a qualitative research method and as a data collection component in multi-method health research projects. Training will also include information about the key characteristics of focus groups (trained facilitators, semi-structured discussions, etc), facilitator and co-facilitator roles, and logistical and group management issues. Focus group staff will be trained on the process of note-taking during the groups for purposes of later identification of individual speakers, and on methods for analyzing transcripts. Each site is charged with ensuring inter-rater reliability with respect to coding of the transcripts. Focus group staff should also be familiar with the particular domain being studied, including its formal definition and items currently in the bank to ensure informed facilitating. Domain

subgroups should advise staff of any conceptual challenges or nuances that may need detailed study.

c) Focus Group Procedures

The focus groups will be held at times convenient to the participants. Patients will be asked in advance to commit to approximately 2 hours of time participating in the project. On the day of the focus group, the procedure will be as follows:

Informed consent should be obtained prior to the initiation of the group process, enabling each participant the opportunity to ask questions regarding the purpose of the group activity and the risk/benefit equation. (see Appendix B6) It is preferable to consent participants prior to the day they arrive for the group, but consenting upon arrival is allowed. After providing consent, participants will complete a sociodemographic form (Appendix B7) that contains information on the participant's age, gender, ethnicity, living situation, employment, and education. Additional clinical information is also captured on the sociodemographic form regarding the patient's duration of disease and treatment. The data from the sociodemographic questionnaires will help to characterize the focus group populations. This form is also ideally completed prior to starting the group. Information from the completed sociodemographic forms will be returned to the SCC using an online data collection process. This will not include patient names.

The initial group discussion will concentrate on clarifying the project purpose and protecting confidentiality. Members will be asked to agree that discussion of topics raised over the next 2 hours be "left behind" in the room rather than carried on between members after the group is finished. It will be emphasized that this is requested primarily to encourage people to speak openly and freely during their discussion time together.

Two or three focus group staff members (facilitator and co-facilitator/s) will be present during each focus group. The facilitator will work from a semi-structured interview format with open-ended questions to elicit group participation and discussion on specific topic areas. A sample introductory script for the patients is included in Appendix B8 and the discussion guide is provided in Appendix B9. These guides include questions that will be asked in the sessions as well as follow-up queries and prompting. Specific

questions are designed to facilitate focused discussion and optimize consistency across focus groups for shared issues. The facilitator will solicit participation and keep the discussion “on topic,” but will otherwise maintain a nondirective, supportive and non-evaluative stance. The goal is to obtain insights into the attitudes, perceptions and opinions of participants solicited through the open-ended, semi-structured discussion format.

Each PRS focus group site will obtain IRB approval for focus group procedures, which will take precedence over this protocol. All focus group sessions will be audio-recorded, transcribed and textually analyzed at the PRS using a qualitative software package [*e.g., Atlas.ti, Nudist, Ethnograph*]. An independent rater (not the focus group leaders) will also conduct a content analysis to systematically identify themes and to categorize them into logical thematic groupings. Consensus will be obtained on the topics that emerge from the interviews. See section V.D.6 Qualitative Analysis for more details. Data about the group including a summary of themes will be transferred to the SCC using an online data collection process.

Upon completion of the group, each participant may be tested with the Wide Range Achievement Test (WRAT) to provide a measure of literacy and will be compensated according to the provision of the IRB-approved consent form.

5. Participant Withdrawal

Participants will be informed that they may withdraw from the study at any time. Participants who withdraw participation during the group are typically offered the same compensation without prejudice. Participants are also free to discontinue participation in the focus group at any time. They will be offered the same compensation as those who completed the group.

6. Qualitative Analysis

Content analysis will be used to evaluate the information gathered during the focus groups. The analysis will be based on recall, notes taken by the co-facilitator, and transcripts from session recordings. The evaluation process will include the following: 1) generation of key words, phrases, and quotes regarding symptoms, concerns or fears

about the domain under discussion; 2) identification of additional, emergent themes in each of the PROMIS item content domains relevant to their current health; and 3) important other issues not covered by the initial five selected health domains. To be considered credible, themes included in the final analysis should be concerns that were raised by more than one participant in a single group, and, ideally, by participants in more than one group.

E. Ethical Considerations

1. Risks/Benefits

This study involves group interviews for information purposes only and does not involve the use of an investigational drug or device. There are no known physical risks, however during or following the focus group sessions, participants may become more aware of their domain-related problems or other concerns and experience mild transient psychological distress associated with having to recount their symptoms. Patients will be free to share their questions or concerns with the focus group leaders. The elements of federal regulations pertaining to consent procedures, disclosure of potential risks and benefits, and subject confidentiality will be strictly observed.

There are no direct benefits to the focus group participants. While focus groups are not intended to be therapeutic, focus group participants often report that they have felt less alone and emotionally empowered after hearing from other people who have shared similar life (e.g., illness) experiences. Benefits to society might include improved measures of health outcomes that may enable better monitoring of health status and better understanding of ways to adapt care to maximize patients' quality of life.

2. Informed Consent

All participants will provide written informed consent and, if necessary, HIPAA authorization prior to participating in the focus group discussions. The investigator is responsible for ensuring that all participants fully understand the nature and purpose of the study. Participants will be provided with a copy of their signed consent form describing the study, procedures, risks and benefits. Appendix B6 contains a sample Informed Consent Form.

3. Confidentiality

All data collected in this study will be strictly confidential in accordance with local, state, and federal law. Access to the participant files will not be permitted to anyone other than the study staff. Only the study staff involved in participant recruitment and data collection will know the identity of the participants. Study staff will be instructed to maintain complete confidentiality of all collected data. Participant files will be kept in a locked file cabinet and the master list that link patient identifiers to data will be stored separately. Once computerized, all data will be maintained in password protected computers and password protected files accessible only to the investigators on this project. Upon study completion, all participant identifying information and session recordings will be destroyed. The summary report generated from the focus group sessions will not contain any participant identifying information.

Focus group participants should be provided with the opportunity to decide how to identify themselves during the group process (e.g., first name, first and last name, nickname, pseudonym, initials). While the participant-selected identifier will be used during the groups to identify participants, transcripts will include only a participant identification number.

F. Regulatory Considerations

1. Institutional Review Board (IRB) Approval

In accordance with ethical practice and with requirements of most peer-reviewed journals, IRB approval will be obtained to comply with human subjects research requirements prior to administration of measures.

2. Safety Monitoring

No treatment is provided in this study, and therefore no adverse events are expected. Should an adverse event occur, it will be reported using an FDA MEDWATCH form within 24 hours of occurrence.

3. Records Retention

Records will be retained for a minimum of 2 years on-site and an additional 5 years off-site. At the time of enrollment, participants will be assigned unique identification

numbers. Only the unique participant ID will be recorded on the participant questionnaires.

G. References

Krueger, R. A. (1994). *Focus groups: A practical guide for applied research (2nd ed)*. Thousand Oaks, CA: Sage.

Schwarz, N., & Sudman, N. (Eds.). (1996). *Answering questions: Methodology for determining cognitive and communicative processes in survey research*. San Francisco: Jossey-Bass.

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VI. Section C: Cognitive Interviews

A. Protocol Synopsis

Parameters	Participants
Recruitment	Male and female patients will be recruited by each participating PRS according to the method approved by that PRS IRB review. Possible recruitment methods include print media (mail or posted in clinic), email notification, internet posting, clinic or hospital databases.
Number of participants	A minimum of 5 participants will review each item; each interview will include approximately 30 items from one domain. A second round of interviews will be conducted with 3-5 participants for items that were substantially revised after the first round.
Participant Inclusion Criteria	<ol style="list-style-type: none">1. At least 18 years of age;2. Physician diagnosis of a chronic health condition within the last 5 years or experiencing a chronic health condition during the past 5 years (earlier diagnosis)3. Self-reported ability to speak and read English; AND4. Willing to provide signed informed consent
Participant Exclusion Criteria	<ol style="list-style-type: none">1. Having any concurrent medical or psychiatric condition that, in the investigator's opinion, may preclude participation in this study; or2. Cognitive or other impairment (e.g., visual) that would interfere with completing an interview.
Instruments	A sociodemographic questionnaire provided by the SCC [<i>and any other questionnaires that a domain needs to benchmark a patient's status</i>]; one domain's PROMIS item bank; and a semi-structured cognitive-debriefing interview.
Administration of Instruments	Signed informed consent will be obtained when patients are recruited and prior to completion of one-on-one cognitive debriefing interviews. Participants will be compensated according to local IRB submissions for their time upon completion of the cognitive interview. Cognitive debriefing interviews will be audiotaped/or digital voice recorded for quality assurance. For items that have been substantially revised in response to the cognitive debriefing, 3-5 participants will complete a second debriefing interview on those revised items by telephone.
Analysis	Descriptive statistics will be used to characterize the demographics of the sample population. Summarization and content analysis will be used to evaluate open-ended responses on the survey data and for data captured during the cognitive debriefing interviews.

B. Purpose

The cognitive interviewing process generally consists of questions to ascertain: (1) comprehension of the question (i.e., what does the respondent believe the question is asking; what do specific words and phrases in the question mean to the respondent); (2) the processes used by the respondent to retrieve relevant information from memory (i.e., what does the respondent need to recall to be able to answer the question; what strategies does the respondent use to retrieve the information); (3) decision processes, such as motivation and social desirability (i.e., is the respondent sufficiently motivated to accurately and thoughtfully answer the question; is the respondent motivated by social desirability in answering the question); and (4) response processes (i.e., can the respondent match his/her response to the question's response options) (Tourangeau, 1984). Some of these processes may be "conscious," and others are outside the awareness of the respondent (Willis, 1999). There are two major sub-types of cognitive interviewing methods: Think-aloud and verbal probing. The PROMIS cognitive interviews will employ a "retrospective" verbal probing technique. In this technique, a participant completes a paper and pencil version of the questionnaire of interest. A trained interviewer then asks for other, specific information relevant to each question, or "probes further into the basis for the response" (Willis, 1999). Willis (1999) suggests that this type of "retrospective" probing or debriefing is useful when a more "realistic" type of presentation of items is desirable, particularly at later stages of questionnaire development. Additionally, this method reduces probing from biasing patients' responses to items later in the questionnaire.

The aims of the cognitive debriefing project for PROMIS are to (1) assess the content validity of the PROMIS item banks; (2) refine the language of items; and (3) refine response options of items of the PROMIS domain item banks. As it is overly burdensome to the patient to attempt cognitive debriefing with every item in a domain, a sampling scheme will be applied allowing for each participant to be debriefed on approximately 30 items. The 30 items will be representative of most if not all subdomains or bins within a bank. Further, by the completion of the cognitive debriefing phase, all items in the bank will have been reviewed by at least 5 participants. Through semi-structured cognitive debriefing interviews, participants will be asked to provide

feedback regarding response categories, time frame, item interpretation and overall impression of domain content and coverage. Targeted questions designed to assess missing content will help ensure that each domain has adequate coverage throughout its continuum. For this reason as well as to reduce potential conditioning effects from probing, having items representing most, if not all, bins within a subdomain or potential bank is critical.

C. Methods

1. Overview

Each PROMIS domain will conduct domain-specific cognitive debriefing interviews at one or more PROMIS primary research site (PRS). This protocol contains standardized cognitive interviewing methodology that will be applied across all domains. However, each domain group will specify eligibility criteria for participants, may vary in their decisions regarding participant compensation, and will have domain-specific items and probes about those items for respondents to answer. The methodology for data summary and analysis will be similar across domain groups and will be domain-specific only to the extent necessary to accommodate domain-specific content. The following is a brief overview of the participants, procedures, and the approach to be used for evaluating the information gathered during the cognitive debriefing interviews.

2. Participants

Participants for cognitive interviewing will be selected on the basis of experiencing a chronic health condition in the past 5 years. Participants may or may not have experienced a health-related symptom or impairment consistent with the PROMIS domain of interest. All participants will not be recruited from the same disease population, but will represent a range of types of chronic health conditions (e.g., diabetes, chronic pulmonary disease, cardiovascular disease, musculoskeletal disease, chronic pain, chronic gastrointestinal conditions (e.g., irritable bowel syndrome and inflammatory bowel disease), cancer, chronic fatigue syndrome, and fibromyalgia). The sample of participants recruited to participate in the cognitive debriefing interviews should be diverse with respect to sociodemographic, disease, and symptom variables. Thus, the sample should include at least two individuals who have not completed high school or

have cognitive impairment, one African-American/Latino/Pacific Islander/Native American, one Caucasian, one individual with no or mild levels of the domain of interest, and one individual with moderate or high levels of the domain of interest. These categories are not exclusive. For example, a Latina woman with an 8th grade education and severe fatigue would fulfill requirements 1, 2, and 5 for one item set. Appendix C1 is an example form to utilize to track assigning participants to item sets.

a) Inclusion Criteria

In addition to the sociodemographic and disease criteria outlined above, participants must meet all of the following criteria to be eligible for this study:

At least 18 years of age;

Physician diagnosis of a chronic health condition within the last 5 years or experiencing a chronic health condition during the past 5 years (earlier diagnosis);

Self-reported ability to speak and read English; and

Willing to provide signed informed.

b) Exclusion Criteria

Participants meeting one of more of the following criteria are *not* eligible for the study:

Having any concurrent medical or psychiatric condition that, in the investigator's opinion, may preclude participation in this study; or

Cognitive or other impairment (e.g., visual) that would interfere with completing a face-to face interview

3. Recruitment Procedures

Potential participants will be recruited by research staff at the PRS. Participants may be recruited through any of the following mechanisms:

1. Print media or flyer postings (see Appendix C2 for example)
2. Email or internet postings (see Appendix C3 for example)

3. Mailed letters to targeted clinic populations – this may or may not include a postage-paid response card (see Appendix C4 and C5 for examples)

In the case of recruitment through advertisement, all interested respondents will be screened by research staff with a standard screening form (Appendix C6) to confirm eligibility.

Potential participants will be screened for study eligibility by a PRS staff member using a screening script (Appendix C6). Respondents who meet eligibility criteria will be provided further explanation of the study. For respondents who agree to participate, a staff member will fully explain the study to the participant and obtain written informed consent (Appendix C7, sample consent form) according to individual institutional IRB requirements. This discussion should include an estimate of how long the cognitive interview will take. Interviews will then be scheduled at a time convenient for the participant. Participants recruited via print media, e-mail, letters or calls will sign the consent form at the time of their scheduled meeting. Attempts to oversample from underrepresented gender, age and ethnic groups should be made to avoid a narrow demographic pool of participants. Depending on individual site specifications, participants may receive compensation for their time at the close of the interview.

4. Conducting the Cognitive Interviews

a) Overview

Each face-to-face cognitive debriefing interview is expected to last approximately 45-60 minutes. At the debriefing, each participant will complete approximately 30 items. The 30 items will be representative of most subdomains or bins within a bank. No participant will complete all items within any given bank, but all bank items will be reviewed in cognitive interviews by a minimum of five participants.

At the face-to-face interview, after a participant completes a paper and pencil version of the 30 items to be debriefed, a trained interviewer will use a semi-structured interview guide (Appendix C9) involving a series of open-ended questions to elicit the participant's comprehension or interpretation of the item and their preferences or feedback on aspects of the question (e.g., response options). This will be repeated for each item in the item

set. Interviewers will then summarize the qualitative findings from all interviews. Interviews will be audio-taped and stored. Electronic storage of tapes is strongly suggested as this will allow easy access to a given interview by network members at different sites. The SCC can provide equipment recommendations for digital taping and storage.

After completing all interviews for an item, each domain group will decide, on an item-by-item basis, whether the item needs to be revised based on feedback from cognitive debriefing. Domain groups will then revise problematic items. For substantially revised items, three to five participants will review the revised item. The exact number of secondary reviewers will be made based on when saturation is reached. If the third reviewer of revised items does not provide new information, additional reviewers are not needed. Returning participants will be contacted by phone to review the revised items using the debriefing guide for revised items (Appendix C10), which is expected to last approximately 15 minutes (depending on the number of revised items). Participants will not review items included in their initial item set. For example, if a participant completed Item Set A initially, she would be contacted by phone to review the substantially revised items from Item Set B (or C, etc). Participants for this second review may be the original reviewers, new reviewers, or a mixture of both. Note, however, that in order for new participants to complete the literacy assessment requirement, their interviews will need to be face-to-face and not by phone, as the WRAT cannot be administered by phone without modifications. At least one of the secondary reviewers must not have graduated high school or have cognitive impairment (see Appendix C1).

The domain chair will review the revised items and participants' responses from the 2nd review. If an item is no longer considered problematic by research participants in the 2nd review, it may be retained in the item bank and moved forward for testing in patient populations. If an item does not appear to be comprehensible or relevant in the 2nd review, the domain chair is strongly encouraged to eliminate that item from the item bank. If a domain chair wishes to revise an item again following the 2nd review, it should then go through cognitive debriefing with two new participants.

Items are defined as being “substantially revised” if their revision involved more than (1) adding or removing a supportive word or other word that did not change the meaning of a phrase, (2) word substitutions that in the judgment of the reviewer are not more than a semantic simplification, (3) changing the order of words. Examples of “substantially revised” items and non-substantially revised items are in Appendix C11. Note that the determination of what items are “substantially revised” is a subjective judgment of the domain chair.

Each domain group will utilize an online data collection process to transfer information about participants (sociodemographic and clinical) and items (comprehensibility) to the SCC. The SCC will provide reports to the domain groups summarizing participants’ feedback.

The Physical Function (PF) domain will employ a different process of cognitive assessment. The use of two different strategies provides an opportunity to test the two methodologies (paper-and-pencil cognitive assessment versus cognitive interviewing) with respect to differences in number of items rejected, number of items re-written, and how the items perform in testing. This strategy will involve 100 participants, each responding to and commenting on 20-30 candidate items. Participants will complete a set of PF items and then complete a questionnaire to obtain patient ratings on three aspects: item clarity ("How clear is it to you?"), item relevance ("How important is it to you?") and item comprehension (series of probes on how the participant arrived at their response). The domain group will then score items on the number of problems/100 in each of the three areas queried and establish criteria for problematic items (e.g., any problems, over 10 % problems in any category, in most problematic 10 % of items), the specific criteria for which will be determined after seeing the raw data and distributions. The PF domain will then conduct cognitive interviews (using the PROMIS Cognitive Assessment Protocol) on subjects and items where possible problems were identified and on a comparison group of subjects and items where possible problems had not been indicated. The PF subjects are derived from a national sample, precluding face-to-face interviews. Comparisons between the two methodologies will then be conducted. The PF group will transfer data from the interview portion of the assessment to the SCC utilizing the same

process as other domains. In addition to these procedures, several PF items will be included in the cognitive testing protocols of the other PRSs so that a direct comparison of the procedures used by the PF domain and the procedures used by the other PRSs is possible. Specifically, the question of interest here is, do both sets of techniques yield comparable information about patients' reactions to items?

b) Cognitive Interview Staff Training

All cognitive interviewers will have received training on the principles involved in conducting cognitive interviews. This training includes an overview of cognitive interviews as a qualitative research method and as a data collection component in multi-method health research projects. Cognitive interview staff will be trained on the process of note-taking during the interview and summarizing qualitative data. An example of summarized data is included in Appendix C12. Interviewers should have experience relating to (or interacting with) patients and have good interpersonal skills. They should also have sufficient questionnaire design experience so that they can translate interview findings into suggestions for item revision. Interviewers should have been exposed to social science research concepts such as bias, context effects, and measurement and scale effects. Interviewers should be familiar with the domain being studied, including its formal definition and items currently in the complete bank.

c) Cognitive Interviewing Procedures

In the retrospective verbal probing technique of cognitive interviewing, the participant completes the questionnaire independently. The interviewer will then follow the semi-structured cognitive interview guide asking for specific information relevant to the question or to the specific answer given. Probes in the interview guide (Appendix C9, C10) are based on categories of cognitive probes outlined by Willis (1999), as presented below with examples:

- Comprehension/interpretation probe: What does the term “xxx” mean to you?
- Paraphrasing: Can you repeat the question I just asked in your own words?
- Confidence judgment: How sure are you that [*you are able to walk a block?*]

- Recall probe: How do you remember that you had pain for 5 of the last 7 days?
- Specific probe: Why do you think [cancer is the most serious health problem?]
- General probes: How did you arrive at that answer? Was that easy or hard to answer? I noticed that you hesitated – tell me what you were thinking.

The cognitive interviews will be held at times convenient to the participants. Patients will be asked in advance to commit to approximately 1.5 hours of time participating in the project. On the day of the interview, the procedure will be as follows:

Original Debriefing Interview Order of Administration:

- A) The first 10-15 minutes will be devoted to the informed consent process, including a review and signing of the consent form (Appendix C7).
- B) All participants will be administered the WRAT as a gross measure of literacy level.
- C) Participants will complete the item set through paper and pencil administration independently. A staff member will then debrief participants using standardized debriefing questions (Appendix C9). All sessions will be audio-taped with recordings stored in a secure location.

Participants will then complete a sociodemographic form (Appendix C8) that contains information on the participant's age, gender, ethnicity, living situation, employment, and education. Additional clinical information is also captured on the sociodemographic form regarding the patient's duration of disease and treatment. The data from the sociodemographic questionnaires will help to characterize the cognitive interviewing populations. This information will be transferred to the SCC using an online data collection format.

Order of Administration for Debriefing Interview for Revised Items:

For participants who did not participate in the original cognitive debriefing exercise, the informed consent process will be completed prior to scheduling the telephone the interview (Appendix C7). Participants will then complete the debriefing interview, followed by completion of a sociodemographic form (Appendix C8). Participants who were drawn from the original sample of 5 will only need to complete the debriefing exercise.

Each participant will be compensated according to local IRB submissions. If a participant stops before completion for any reason, s/he will still be offered compensation.

5. Participant Withdrawal

Participants will be informed that they may withdraw from the study at any time.

6. Analyses

Content analysis and descriptive summary statistics will be used to evaluate the information gathered during the cognitive debriefing interviews and to characterize the participant sample. The analysis will be based on notes taken by the interviewer and the interview recording (if needed) and done on an item-by-item basis. The interviewer's goals in summarizing responses from participants is to capture participants' comprehension of items, decision processes, response processes, and the information recall ability and recall strategy. This information should be used to either make a suggestion for item revision or pose a question to clarify what the item intends to target.

An example summary follows (Willis, 1999). See also Appendix C12:

“A1. How far do you routinely travel to get health care? Would you say less than an hour, one to two hours, or more than two hours?”

Comments: “Of the four subjects I tested, all had problems answering this question. Three of them objected that this really varied, depending on the type of provider they’re visiting. The fourth one stated that the answer to “how far” would be five miles; not that the question is internally inconsistent, because the

question implies a distance, while the answer categories are all represented by amounts of time.

Finally, it wasn't really clear what the reference period is. One subject had been to the doctor once in the past year or so, and so didn't know how to handle the "routine" part, or how far back he should go in thinking about an answer. We really need to re-think whether we want to know how long it takes people to see the provider they saw the most during the past X months, or how long it takes them when they go for a routine check-up (assuming they do), or something else entirely."

D. Ethical Considerations

1. Potential Risks/Benefits

This study involves participant questionnaires and interviews for information purposes only and does not involve the use of an investigational drug or device. There are no known risks, however during or following the interview, participants may become more aware of their medical condition and experience mild transient psychological distress associated with having to reflect on issues that are difficult to talk about. Participants will be free to share their questions or concerns during the interview. The elements of federal regulations pertaining to consent procedures, disclosure of potential risks and benefits and subject confidentiality will be strictly observed.

There are no direct benefits to the cognitive interview participants. Answering the questions might help the respondents to think about things related to their condition that may be important to them. Benefits to society might include improved measures of health outcomes that may enable better monitoring of health status and better understanding of ways to adapt care to maximize patients' quality of life.

2. Informed Consent

All participants will provide written informed consent and, if necessary, HIPAA authorization prior to participating in the cognitive interview. The investigator is responsible for ensuring that all participants fully understand the nature and purpose of the study. Participants will be provided with a copy of their signed consent form

describing the study, procedures, risks and benefits. Appendix C7 contains a sample Informed Consent Form.

3. Confidentiality

All data collected in this study will be kept strictly confidential in accordance with local, state, and federal law. Access to the participant files will not be permitted to anyone other than authorized study personnel. Only the study staff involved in participant recruitment and data collection will know the identity of the participants. Study staff will be instructed to maintain complete confidentiality of all collected data. Participant files will be kept in a locked file cabinet or in a secured password-protected electronic environment, and the master list that link patient identifiers to data will be stored separately. Upon study completion, all identifying participant information and session recordings will be destroyed. The summary report generated from the cognitive debriefing interviews will not contain any identifying participant information.

E. Regulatory Considerations

1. Institutional Review Board (IRB) Approval

In accordance with ethical practice and with requirements of most peer-reviewed journals, IRB approval will be obtained to comply with human subjects research requirements prior to administration of measures.

2. Safety Monitoring

No treatment is provided in this study, and therefore no adverse events are expected. Should an adverse event occur, it will be reported using an FDA MEDWATCH form within 24 hours of occurrence.

3. Records Retention

Records will be retained for a minimum of 2 years on-site and an additional 5 years off-site. At the time of enrollment, participants will be assigned unique identification numbers. Only the unique participant ID will be recorded on the participant questionnaires.

F. References

- Tourangeau, R. (1984). Cognitive sciences and survey methods. In T. Jabine, M. Straf, J. Tanur, & R. Tourangeau (Eds.). Cognitive Aspects of Survey Methodology: Building a Bridge Between Disciplines, pp. 730-199, Washington, DC: National Academy Press.
- Willis, G.B. (1999). Cognitive Interviewing: A “How To” Guide. From the short course “Reducing Survey Error through Research on the Cognitive and Decision Processes in Surveys,” presented at the Meeting of the American Statistical Association.

APPENDIX A1: PROMIS Network Preferred Response Sets
AS OF 9/27/2005

<p><u>Frequency #1</u> Never Rarely Sometimes Often Always</p>
<p><u>Frequency #2</u> Never Once a week or less Once every few days Once a day Every few hours</p>
<p><u>Duration #1</u> A few minutes Several minutes to an hour Several hours A day or two More than 2 days</p>
<p><u>Duration #2</u> None 1 day 2-3 days 4-5 days 6-7 days</p>

<p><u>Intensity #1 (severity)</u> None (or Had no pain) Mild Moderate Severe Very Severe</p>
<p><u>Intensity #2 (or interference)</u> Not at all A little bit Somewhat Quite a bit Very much</p>
<p><u>Difficulty</u> Without difficulty With some difficulty With much difficulty Unable to do</p>
<p><u>Other</u> Strongly disagree Disagree Agree Strongly Agree</p>

APPENDIX B1: Example Flyer Recruitment Posting
(Sent by site to potential participants)

VOLUNTEERS NEEDED!

Looking for [*condition*] to participate in a Focus Group Research Study

You may be eligible to participate in a small group discussion on how the health issues relate to quality of life.

**Must be:
[insert eligibility criteria]**

Compensation for your time and travel expenses is available.

FOR FURTHER DETAILS CONTACT

[phone number]

or

Email [\[email address\]](#)

PROMISc Focus Group
[EMAIL ADDRESS]
[PHONE NUMBER]

PROMISc Focus Group
[EMAIL ADDRESS]
[PHONE NUMBER]

PROMISc Focus Group
[EMAIL ADDRESS]
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PROMISc Focus Group
[EMAIL ADDRESS]
[PHONE NUMBER]

APPENDIX B2: Sample Internet Recruitment Posting

Website Posting
[\[http://insert website here\]](http://insert website here)

Study number: IRB study #: [*insert IRB approval number*]

Title of Study: PROMIS Patient Reported Outcomes Focus Groups

Principal Investigator: [*insert PI name*]

Description:

The purpose of this research study is to learn more about how health issues relate to patients' quality of life. [*Insert specific description of focus group*] The reason for collecting this information is to find ways to improve health-related quality of life for specific groups of patients and their families. Information from the focus groups will be used to develop surveys used to compare the quality of life concerns of people who have [*condition*] with those who do not have any chronic diseases. Approximately [*insert number*] participants will be enrolled in this project.

Contact: [*insert phone number*]

[*insert email address*]

Requirements: [*insert eligibility criteria*]

The discussion in the focus group will be in English.

Time commitment: approximately 2 hours

Compensation: Each participant will receive a [*incentive*] and be reimbursed for mileage and parking.

APPENDIX B3: Participant Introductory Letter
(Sent by site to potential participants)

INTRODUCTORY LETTER

[Date]

[Name]

[Address]

Re: Invitation to patients to participate in a Focus Group Discussion

Dear [Patient]:

The [*site name*] is participating in a study to learn more the experience and impact of having [*condition*]. To do this, [*site name*] will be conducting [*number of focus groups*] focus groups (or group discussions) with 6 to 12 eligible participants in each session. The information shared by members in these facilitated group discussions will help healthcare researchers gain a better understanding of the experience and impact of having [*condition*]

Participation is entirely voluntary. If you are at least 18 years of age, have been diagnosed with... from [*condition*] and are currently [*enrollment criteria*], then you could be invited to participate in a one-time group discussion that will last approximately 1 ½ - 2 hours. The discussions will be held in a location near our clinic and arranged at a time convenient for most people to attend. You will be given a [*incentive*] for your participation in the focus group session.

If you wish to be part of this study, please complete the enclosed, pre-stamped and addressed postcard and mail it to our office. When we receive your postcard, one of my research staff members will contact you by phone. The staff person will ask you a few questions to confirm your eligibility for this project. If you are eligible to participate, you will be contacted soon afterwards regarding potential dates and times for the focus groups. If you do not wish to participate, you may mark the box on the postcard and send it back or simply do not return the postcard. We will not contact you any further regarding this study.

We hope that you will be interested in being part of this study. This opportunity to discuss your experience with [*condition*] may help others in the future.

Sincerely,

[*site PI or clinic Investigator*]

APPENDIX B4: Response Postcard

RESPONSE POSTCARD

Interested participants will send this back to the site.

Screening ID: _____

Please check the appropriate box:

- I received your letter about the study and I am interested in participating. Please contact me to provide more information.
- I am not interested in participating.

Initials: _____

Phone number: _____

APPENDIX B5: Screening Form

SCREENING FORM

Contact name:

Date of contact:

Unable to contact:

Date(s)/Times of calls:

Follow-up steps:

[Start with standard phone greeting, introduce self and confirm that you are talking to person who expressed interest in the study]

Thank you for responding to the [*insert type of recruitment mechanism*]. As you know, the [*site name*] is participating in a study to learn more the experience and impact of having [*condition*]. [*insert paragraph describing the study from IRB approved informed consent*]

[*site name*] is recruiting patients to participate in these group discussions. To find out if you are eligible for this study, may I ask a few questions?

If no, then thank for interest and terminate. If yes, proceed.

1. What is your date of birth? <i>If under 18, not eligible</i>	____ / ____ / ____ month day year
2. Have you been diagnosed with [<i>condition</i>]	Yes <input type="checkbox"/> No <input type="checkbox"/>
3. [<i>insert other eligibility criteria</i>]	Yes <input type="checkbox"/> No <input type="checkbox"/>

To be eligible for the group, the participant **must**:

- Be ≥ 18 years of age
- Respond YES to item 2
- Respond YES to item 3.

If ineligible, thank and terminate the call.

The following statement should be used at any point during the call that the person is found to ineligible.

“Thank you for your interest in the study, however, based on your answers to my questions, you are not eligible to participate.”

If eligible, continue

Based on the answers that you just gave me, you are eligible to participate in a group discussion on the experience and impact of [condition]. If you choose to participate, you will be asked to participate in a group discussion with people with similar experiences. The group discussions will be held at [location] and should take approximately 1 ½ to 2 hours to complete. Upon completion of the focus group, you will receive a [incentive] for your time.

If the participant is not interested, thank and terminate the call.

If interested, continue.

A research staff member will contact you shortly with the possible dates that these focus groups will be held and to determine times you would be available to attend. In addition, we will also mail you directions to the focus group location. Can I have your address?

Patient name: _____

Telephone number: (____) _____

Mailing address: _____

Do you have any questions? If yes, we will have the researcher contact you as soon as possible to discuss. Thank you again, and I look forward to talking with you in the future.

Thank you very much for your time. Have a nice day!

APPENDIX B6: Draft Informed Consent Form

[It is understood that consent forms will be site-specific. This template is provided only as a guide. Each site conducting focus groups will need to tailor this consent form to meet its institutions IRB and HIPAA requirements.]

Informed Consent Form

PROMIS Patient Focus Groups for [CONDITION]

Principal Investigator: [site PI]
[site name]

Co-Investigator: [site Co-PI]
[site name]

INTRODUCTION

You have been invited to participate in a research study. This consent form informs you about the purpose, procedures, possible risks and discomforts, and benefits of the study. You are free to choose whether or not you would like to participate. If you decide to participate after reading this form, please initial and date the first 2 pages in the space provided at the bottom and sign the form on the last page.

PURPOSE

The purpose of the study is to learn more the experience and impact of having [condition].

PROCEDURE

If you agree to participate, you will be asked to participate in a group discussion about your experience with [condition] and the impact [condition] has had on your life. The discussion will last approximately 1½ to 2 hours and will be audio-recorded. The recordings will be reviewed by the researchers to gain a full understanding of your experiences.

RISKS AND DISCOMFORTS

There are no known risks associated with participating in this study, although you may feel awkward talking about how your [condition] affects your life. Please feel free to share your questions or concerns with the group moderator before, during, or after the focus group discussion.

BENEFITS

You will not receive any medical benefit from participating in this study; however, you may feel better after talking about your feelings. Additionally, what is learned from these discussions may help other people in the future who have similar concerns about their [condition].

Participant's Initials: _____

Date: _____

ALTERNATIVE

You have the alternative to not participate in this study.

COSTS

There are no costs for you to be in this study.

COMPENSATION

You will [*incentive*] for your participation.

CONFIDENTIALITY

This study can be performed only by collecting and using some of your personal medical information. Your study records will be kept as confidential as possible under local, state, and federal laws. Personnel from the following organizations may examine your records: [*Each focus group site should check with their institution’s IRB, as this could include all PROMIS institutions OR could be referred to in aggregate, e.g., “PROMIS institutions”; please consult SCC if questions arise*] and the Institutional Review Board (IRB), a committee that has reviewed this study to help ensure your rights and welfare as a research participant are protected and that the study is carried out in an ethical manner. Because of the number of individuals who may see your records, absolute confidentiality cannot be guaranteed.

Personal information that may be used and disclosed includes that which is obtained to determine your eligibility and collected from the procedures that are carried out. It may identify you by name, address, telephone number, study number, date of birth, or other identifiers. If the final study data are prepared for publication, your identity will not be revealed. Under federal privacy regulations, you have the right to see and copy any of the information gathered about you, until it is no longer kept by the study doctor. You may cancel your authorization to use or disclose your personal information, except for that which has already been collected, by sending a written notice to [*insert PIs name*] at [*name of institution*] [*phone number*]. If you withdraw from the study, the information collected to that date may still be used to preserve the scientific integrity of the study. Once the information is disclosed, it is possible it may be disclosed again, at which times it may be no longer protected by federal regulations, but may be by state law.

By signing this consent form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses and disclosures, you will not be able to participate in the study. This authorization does not have an expiration date.

WITHDRAWAL

You may refuse to participate or withdraw at any time without penalty or giving up any benefits to which you are otherwise entitled. If you choose not to participate, your current or future medical treatment at [*site name*] will not be affected.

Participant’s Initials: _____

Date: _____

QUESTIONS

If you have questions about the study, you may write [*name of PI*] at [*address*] or call [*phone number*]. If you have questions about your rights as a research subject, you may write the Institutional Review Board at [*address of IRB*] call [*phone number*]. Review and approval of this study by IRB is not an endorsement of the study or its outcome.

CONSENT

I have read the information on this form. All of my questions about the study have been answered to my satisfaction. I will be given a copy of this signed form to keep for my records. I voluntarily agree to participate in this study.

Type/Print Participant's Name

Date

Participant's Signature

PRINCIPAL INVESTIGATOR (PI):

WITNESS:

PI Name: _____
(Print)

Witness Name: _____
(Print)

PI Signature

Date: _____

Witness Signature

Date: _____

[NOTE: If focus groups are to be audio-taped and/or observed via observation rooms, these procedures typically must be stipulated in the consent form.]

APPENDIX B7: Demographic Profile Questionnaire

SOCIODEMOGRAPHIC FORM

Please answer the following questions. Complete the blanks or check the boxes next to the category that best describes your situation.

1. Today's Date:

1. / /
mm dd yyyy

2. What is your date of Birth?

2. / /
mm dd yyyy

3. Gender:

₁ Male ₂ Female

4. Are you of Spanish/Hispanic/Latino origin?

₁ No ₂ Yes

5. What is your racial or ethnic background? *(Please check all that apply)*

- ₁ White
- ₂ Black or African-American
- ₃ American Indian/Alaska Native
- ₄ Asian
- ₅ Native Hawaiian/Other Pacific Islander

6. What is your current relationship status?

- ₁ Never married
- ₂ Married
- ₃ Living with partner in committed relationship
- ₄ Separated
- ₅ Divorced
- ₆ Widowed

7. What is the highest grade in school that you completed?

- ₁ 5th grade or less
- ₂ 6th grade
- ₃ 7th grade
- ₄ 8th grade
- ₅ Some high school
- ₆ High school grad/GED
- ₇ Some college/Technical degree/AA
- ₈ College degree (BA/BS)
- ₉ Advanced degree (MA, PhD, MD)

8. What is your current occupational status?

- ₁ Homemaker
- ₂ Unemployed
- ₃ Retired
- ₄ On disability
- ₅ On leave of absence
- ₆ Full-time employed
- ₇ Part-time employed
- ₈ Full-time student only

9. What is your family household income (from all sources):

- ₁ Less than \$20,000
- ₂ Between \$20,000 and \$49,999
- ₃ Between \$50,000 and \$99,999
- ₄ \$100,000 or more

[Additional information is likely to be domain-specific but may include:

Diagnosis:

Date of diagnosis:

Disease or symptom severity:

Comorbidities: (?)]

APPENDIX B8: Introductory Script for Focus Groups

INTRODUCTORY SCRIPT FOR PATIENT FOCUS GROUPS

BACKGROUND

Hello and welcome [Introduce self and co-moderator]

Thank you for taking the time to join our discussion about *[domain name]* and the effect of your condition and its treatment upon it. Everyone here today/tonight was invited because you share something in common related to *[domain]*. Our goal is to work from that common ground and learn more from you about how to better understand *[domain]* and how it can be measured with simple questions.

We're primarily interested in finding out about your experience with *[domain]* (for example, symptoms) and concerns you may have about your health condition or treatment. There are no right or wrong answers, because everyone experiences things differently. Some of you may have had more severe symptoms than others. We are interested in the full range of experiences, so please feel free to share your point of view even if it differs from what others have said.

DISCUSSION GROUP RULES

Before we begin, let me suggest some guidelines that will make our discussion more productive.

- Please speak up—but only one person should talk at a time. We're recording the session because we don't want to miss any of your comments. If you have trouble hearing any of the comments, please let the group know.
- In the discussion, we'll be on a first-name basis. In our reports of the results no names will be attached to any comments. Your name will be kept confidential. We've placed name cards on the table in front of you just to help us remember each other's names during the course of the evening.
- My role here is to ask questions and to listen. I'll also be summarizing information on the white board at times. I won't be actively participating in the conversation, only guiding it. I want you to feel free to talk to the group and not just to me. I'll ask questions about the impact your health condition has upon *[domain]*. We are interested in your experiences, but because this is a research project, it is important that you link your comments back to the questions. I'll move the discussion from one question to the next to try to keep us on track so that we can finish by *[insert time]*.
- There are just a few other things that I want to let you know. First, neither *[insert name of other focus group leader]* nor I are medical doctors, so we are not qualified to give out medical advice. Secondly, we will present your compensation to you at the conclusion of the discussion.

- Sometimes, people in focus groups think of things they want to say after the discussion has moved on to other questions. If you would like to add to your comments after the group, we will be around to talk with you privately.
- Any questions before we begin?

APPENDIX B9: Discussion Guide for Focus Group

FOCUS GROUP DISCUSSION GUIDE FOR [DOMAIN]

Each focus group discussion guide is specific to the research question and condition of the study. As such, no specific questions are presented, however guidelines to consider when developing a discussion guide are summarized below.

GENERAL

The interview discussion guide sets the agenda for the focus group discussion, but depending upon the flow of the discussions, the guide should flow as needed with the caveat that all necessary issues are covered by the end of the session. The discussion guide is generated from the research questions and goals of the focus groups.

When generating questions for the discussion guide, consider the following:

1. Start with more general questions first and move to more specific questions;
2. If sensitive topics are to be discussed (e.g. sexual impact, incontinence, etc), start with non-threatening, less personal issues and move to more personal and sensitive issues after the group has developed a rapport and trust among themselves and the moderator;
3. Questions should be presented in the order of importance, however this needs to be considered in light of points 1 and 2 and the length of time for the focus groups. (Focus group discussions should not extend past 2 hours; 90 minutes to 2 hours is optimal).
4. Questions should be open-ended, e.g. “How does {condition} make you feel?” or “How does {condition} affect you on a personally / socially / physically?”
5. Avoid introducing a response with the question (e.g. “Does having [PROBLEM IN DOMAIN AREA] make you angry?”) or providing leading questions (e.g. so you think that xxxx is a bad thing?)
6. Don’t be afraid to follow-up on interesting issues that may not be included in the discussion guide. The point of qualitative research is as a theory-generating, fact-finding exercise. Thus, if participants discuss issues that were not included in the discussion guide but are pertinent to the research questions and goals, follow their lead, but avoid getting lost on a tangential discussion that is not relevant to the research questions.
7. Keep the questions simple and meaningful; avoid long, complex sentences

8. Avoid potentially embarrassing or intimidating questions such as: “Why didn’t you follow your physician’s recommendations?” This could be asked as: “What factors interfered with you following your physician’s recommendations?”

In terms of the number of questions needed, this will vary depending upon the topic and patient group. If the group is to be widely heterogeneous, fewer questions may be needed as the group may offer great variation in responses. If the group is homogeneous, the opposite may be true. Every focus group differs which is why discussion guides are guides which are meant to be flexible. The important thing for each focus group is to cover the essentials first.

APPENDIX C1: Sample Participant Assignment to Item Set

Participant Assignment to Item Set

Domain _____

Initial Review

Item Set	< High school education /cognitive impairment	< High school education/cognitive impairment	African American/ Latino/ Pacific Islander/ Native American	Caucasian	None or mild level of domain	Moderate or severe level domain	Other Participant	Other Participant	TOTAL Number of Participants
A	101	102	101	103	102	103	104	105	5
B	106	107	108	106	108	107	109	110	5
C									
D									
E									

Secondary Review of Revised Items

Item Set	< High school education /cognitive impairment	Other Participant	Other Participant	Other Participant	Other Participant	<i>TOTAL Number of Participants</i>
A	106	107	108			3
B	101	102	103	104	105	5
C						
D						
E						

APPENDIX C2: Example Flyer Recruitment Posting

(Sent by site to potential participants)

VOLUNTEERS NEEDED!

Looking for individuals experiencing [*domain*] to participate in a quality of life research study

You may be eligible to participate in a study asking questions on how your health issues affect your quality of life.

To be eligible for the study you must be:

- At least 18 years old
- Diagnosed with a chronic health condition in the past 5 years
 - Able to speak and read English
- [*insert other eligibility criteria*]

Compensation for your time and travel expenses is available (if applicable).

FOR FURTHER DETAILS CONTACT

[*phone number*]

OR

Email [\[*email address*\]](#)

PROMIS Research Study
[EMAIL ADDRESS]
[PHONE NUMBER]

PROMIS Research Study
[EMAIL ADDRESS]
[PHONE NUMBER]

PROMIS Research Study
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PROMIS Research Study
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[PHONE NUMBER]

APPENDIX C3: Sample Internet Recruitment Posting

Website Posting

[\[http://insert website here\]](http://insert website here)

Study number: IRB study #: *[insert IRB approval number]*

Title of Study: **Content Validity Assessment of the PROMIS Item Bank for** *[domain name]*

Principal Investigator: *[insert PI name]*

Description:

The purpose of this research study to learn more about how health issues relate to patients' quality of life and to obtain feedback from patients regarding the best questions to ask patients who experience *[domain]*. The reason for collecting this information is to find ways to improve health-related quality of life for specific groups of patients and their families. Information from this project will be used to develop questionnaires used to compare the quality of life concerns of people who experience *[domain]* with those who do not have any chronic diseases. Approximately *[insert number]* participants will be enrolled in this project.

Contact: *[insert phone number]*
[insert email address]

Requirements: *[insert eligibility criteria]*

Time commitment: *[approximately 45-60 minutes for the initial interview. Approximately 15-30 minutes for the follow-up phone interview]*

Compensation: Each participant will receive a *[incentive]* and be reimbursed for mileage and parking (if applicable)

APPENDIX C4: Participant Introductory Letter
(Sent by site to potential participants)

INTRODUCTORY LETTER

[Date]

[Name]

[Address]

Re: Invitation to patients to participate in a quality of life research study

Dear [Patient]:

The [*site name*] is participating in a study to learn more the experience and impact of experiencing chronic health conditions. To do this, [*site name*] will be conducting one-on-one interviews with patients in order to determine the best questions healthcare providers should be asking patients in terms of how their health condition has affected their quality of life. The information shared will help healthcare researchers gain a better understanding of the experience and impact of [*domain*].

Participation is entirely voluntary. If you are at least 18 years of age, have been diagnosed by a physician with a chronic health condition in the past 5 years, and are currently [*enrollment criteria*], then you could be invited to participate in a research study. The initial session will last 60 minutes. Participants will complete a brief questionnaire and a one-to-one interview at a location near our clinic and arranged at a time convenient to them. You may be invited to participate in a follow-up phone call that would last approximately 30 minutes. Each participant will be given a [*incentive*] for their participation.

If you wish to be part of this study, please complete the enclosed, pre-stamped and addressed postcard and mail it to our office. When we receive your postcard, one of my research staff members will contact you by phone. The staff person will ask you a few questions to confirm your eligibility for this project. If you are eligible to participate, you will be contacted soon afterwards regarding potential dates and times convenient to you. If you do not wish to participate, you may either mark the box on the postcard and send it back, or simply not return the postcard. We will not contact you any further regarding this study.

We hope that you will be interested in being part of this study. This opportunity to discuss your experience with your health condition may help others in the future.

Sincerely,

[*site PI or clinic Investigator*]

APPENDIX C5: Response Postcard

RESPONSE POSTCARD

Interested participants will send this back to the site.

Screening ID: _____

Please check the appropriate box:

- I received your letter about the study and I am interested in participating. Please contact me to provide more information.
- I am not interested in participating.

Initials: _____

Phone number: _____

APPENDIX C6: Screening Form

SCREENING FORM

Contact name:

Date of contact:

Unable to contact:

Date(s)/Times of calls:

Follow-up steps:

[Start with standard phone greeting, introduce self and confirm that you are talking to person who expressed interest in the study]

Thank you for responding to the [*insert type of recruitment mechanism*]. As you know, the [*site name*] is participating in a study to learn more the experience and impact of having [*domain*]. We are interested in talking with both individuals who have experienced [*domain*] and those who have not. [*Insert paragraph describing the study from IRB approved informed consent*]

[*site name*] is recruiting patients to participate. To find out if you are eligible for this study, may I ask a few questions?

If no, then thank for interest and terminate. If yes, proceed.

1. What is your date of birth? <i>If under 18, not eligible</i>	_____ / _____ / _____ month day year
2. Have you been diagnosed with a chronic health condition by a physician in the past 5 years? (e.g., diabetes, chronic pulmonary disease, cardiovascular disease, musculoskeletal disease, chronic pain, chronic gastrointestinal conditions like irritable bowel syndrome and inflammatory bowel disease, cancer, chronic fatigue syndrome, fibromyalgia)	Yes <input type="checkbox"/> No <input type="checkbox"/>
3. Do you experience [<i>domain</i>]	Yes <input type="checkbox"/> No <input type="checkbox"/>
a. Is your difficulty with [<i>domain</i>] mild, moderate, or severe?	<input type="checkbox"/> ₁ mild <input type="checkbox"/> ₂ moderate <input type="checkbox"/> ₃ severe
4. Are you of Spanish/Hispanic/Latino origin?	Yes <input type="checkbox"/> No <input type="checkbox"/>

5. What is the highest grade you completed?	<input type="checkbox"/> 1 6 th grade or lower <input type="checkbox"/> 2 7 th or 8 th grade <input type="checkbox"/> 3 9 th – 11 th grade (some HS but not HS grad) <input type="checkbox"/> 4 HS degree/GED <input type="checkbox"/> 5 Some college <input type="checkbox"/> 6 College degree <input type="checkbox"/> 7 Postgraduate degree
6. What is your racial or ethnic background? (May select more than one response)	<input type="checkbox"/> 1 White <input type="checkbox"/> 2 Black or African-American <input type="checkbox"/> 3 American Indian/Alaska Native <input type="checkbox"/> 4 Asian <input type="checkbox"/> 5 Native Hawaiian/Other Pacific Islander
7. [insert other eligibility criteria]	Yes <input type="checkbox"/> No <input type="checkbox"/>

To be eligible for the group, the participant **must**:

- Be ≥ 18 years of age
- Respond YES to item 2

Any response on items 3 through 7 is eligible (pending study need)

If ineligible, thank and terminate the call.

The following statement should be used at any point during the call that the person is found to ineligible.

“Thank you for your interest in the study, however, based on your answers to my questions, you are not eligible to participate.”

If eligible, continue

Based on the answers that you just gave me, you are eligible to participate in this research on the experience and impact of [domain]. If you choose to participate, you will be asked to complete some questionnaires and to provide feedback about the questions via a face-to-face interview. Participants complete the forms or interview at [location] and should take approximately 45-60 minutes to complete. Some participants will be asked to participate in a follow-up phone call that will last approximately 15-30 minutes. Upon completion, you will receive a [incentive] for your time.

If the participant is not interested, thank and terminate the call.

If interested, continue.

A research staff member will contact you shortly if we would like you to participate in this study. The staff member will help determine a good date and time for you to come in to the clinic. In addition, we will also mail you directions to the location if needed. Can I have your address?

Patient name: _____

Telephone number: (____) _____

Mailing address: _____

Do you have any questions? If yes, we will have the researcher contact you as soon as possible to discuss.

Thank you again, and I look forward to talking with you in the future.

APPENDIX C7: Draft Informed Consent Form

[It is understood that consent forms will be site-specific. This template is provided only as a guide. Each site will need to tailor this consent form to meet its institutions IRB and HIPAA requirements.]

Informed Consent Form

PROMIS Content Validity Assessment for [DOMAIN]

Principal Investigator: [site PI]
[site name]

Co-Investigator: [site Co-PI]
[site name]

INTRODUCTION

You have been invited to participate in a research study. This consent form informs you about the purpose, procedures, possible risks and discomforts, and benefits of the study. You are free to choose whether or not you would like to participate. If you decide to participate after reading this form, please initial and date the first 2 pages in the space provided at the bottom and sign the form on the last page.

PURPOSE

The purpose of the study is to learn more the experience and impact of having [domain] .

PROCEDURE

If you agree to participate, you will be interviewed by a trained research assistant. You will be asked questions about your experience with [domain] and the impact [domain] has had on your life. You will also be asked to provide feedback on the questions that you answer. The face-to-face interview is expected to last 45-60 minutes will be audio-recorded. The recordings will be reviewed by the researchers to gain a full understanding of your experiences. You may also be asked to participate in a follow-up phone call similar to the face-to-face interview. This will last 15-30 minutes.

RISKS AND DISCOMFORTS

There are no known risks to participating in this study. After completing the interview you may become more aware of your feelings regarding your condition or symptoms. Although it is unlikely, some of the questions you will be asked may be mildly upsetting to you since they reflect issues that may be difficult to talk about. You are free to share your questions or concerns during the interview or to speak with the interviewer following the discussion.

BENEFITS

The information gathered through the interview will help us refine our new questions. Answering the questions might help you think about important issues related to your condition, and the questions may also be interesting to answer. Your participation in the study will assist researchers in refining questions for future use with other patients in office-based and research settings.

Participant's Initials: _____

Date: _____

ALTERNATIVE

You have the alternative to not participate in this study.

COSTS

There are no costs for you to be in this study.

COMPENSATION

You will [*incentive*] for your participation.

CONFIDENTIALITY

This study can be performed only by collecting and using some of your personal medical information. Your study records will be kept as confidential as possible under local, state, and federal laws. Personnel from the following organizations may examine your records: [*Each focus group site should check with their institution's IRB, as this could include all PROMIS institutions OR could be referred to in aggregate, e.g., "PROMIS institutions"; please consult SCC if questions arise*] and the Institutional Review Board (IRB), a committee that has reviewed this study to help ensure your rights and welfare as a research participant are protected and that the study is carried out in an ethical manner. Because of the number of individuals who may see your records, absolute confidentiality cannot be guaranteed.

Personal information that may be used and disclosed includes that which is obtained to determine your eligibility and collected from the procedures that are carried out. It may identify you by name, address, telephone number, study number, date of birth, or other identifiers. If the final study data are prepared for publication, your identity will not be revealed. Under federal privacy regulations, you have the right to see and copy any of the information gathered about you, until it is no longer kept by the study doctor. You may cancel your authorization to use or disclose your personal information, except for that which has already been collected, by sending a written notice to [*insert PIs name*] at [*name of institution*] [*phone number*]. If you withdraw from the study, the information collected to that date may still be used to preserve the scientific integrity of the study. Once the information is disclosed, it is possible it may be disclosed again, at which times it may be no longer protected by federal regulations, but may be by state law.

By signing this consent form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses and disclosures, you will not be able to participate in the study. This authorization does not have an expiration date.

WITHDRAWAL

You may refuse to participate or withdraw at any time without penalty or giving up any benefits to which you are otherwise entitled. If you choose not to participate, your current or future medical treatment at [*site name*] will not be affected.

Participant's Initials: _____

Date: _____

QUESTIONS

If you have questions about the study, you may write [*name of PI*] at [*address*] or call [*phone number*]. If you have questions about your rights as a research subject, you may write the Institutional Review Board at [*address of IRB*] call [*phone number*]. Review and approval of this study by IRB is not an endorsement of the study or its outcome.

CONSENT

I have read the information on this form. All of my questions about the study have been answered to my satisfaction. I will be given a copy of this signed form to keep for my records. I voluntarily agree to participate in this study.

Type/Print Participant's Name

Date

Participant's Signature

PRINICIPAL INVESTIGATOR (PI):

WITNESS:

PI Name: _____
(Print)

Witness Name: _____
(Print)

PI Signature

Witness Signature

Date: _____

Date: _____

[NOTE: If interviews are to be audio-taped and/or observed via observation rooms, these procedures typically must be stipulated in the consent form.]

APPENDIX C8: Demographic Profile Questionnaire

SOCIODEMOGRAPHIC FORM

Please answer the following questions. Complete the blanks or check the boxes next to the category that best describes your situation.

1. Today's Date: 1. / /
mm dd yyyy

2. What is your date of Birth? 2. / /
mm dd yyyy

3. Gender: ₁ Male ₂ Female

4. Are you of Spanish/Hispanic/Latino origin? ₁ No ₂ Yes

5. What is your racial or ethnic background? (*Please check all that apply*)

- ₁ White
- ₂ Black or African-American
- ₃ American Indian/Alaska Native
- ₄ Asian
- ₅ Native Hawaiian/Other Pacific Islander

6. What is your current relationship status?

- ₁ Never married
- ₂ Married
- ₃ Living with partner in committed relationship
- ₄ Separated
- ₅ Divorced
- ₆ Widowed

7. What is the highest level in school that you completed?

- ₁ Elementary/primary school
- ₂ Secondary/high school
- ₃ Some college
- ₄ College degree
- ₅ Postgraduate degree

8. What is your current occupational status?

- ₁ Homemaker
- ₂ Unemployed
- ₃ Retired
- ₄ On disability
- ₅ On leave of absence
- ₆ Full-time employed
- ₇ Part-time employed
- ₈ Full-time student only

9. What is your family household income (from all sources):

- ₁ Less than \$20,000
- ₂ Between \$20,001 and \$40,000
- ₃ Between \$40,001 and \$60,000
- ₄ Between \$60,001 and \$80,000
- ₅ \$80,001 or greater

Additional information is likely to be domain-specific but may include:

Diagnosis:

Date of diagnosis *[or duration of experience of domain of interest]*:

Disease or symptom severity:

Comorbidities:

APPENDIX C9: Standardized Debriefing Interview Guide

Standardized Debriefing Interview Guide

Debriefing questions (to be formatted for interviewer administration)

Thank you for completing this set of questions. We are interested in what you thought about the questions and would like to know any ideas that you may have on how to improve the items. After each item, I will ask you your thoughts and opinions about it. Do you have any questions before we begin?

The following are suggested probes.

Time Frame

The current PROMIS time frame is “past 7 days.” Most items are cued to this time frame.

- *What timeframe did you consider when completing these items? What specific days did you include (from what day to what day)?*
- *What strategies did you use to think about the best answer for this time frame? For example, did you recall each event individually or use an estimation strategy?*

Items may need revision if participants are incorrectly identifying the past 7 days (e.g., using the past work week, past calendar week, past single day, most recent few days). Problematic responses in this category are likely to need resolution at the network level to help clarify the time frame of interest on all items.

Items may need to be revised if participants have a difficult time counting or estimating the number of times an event happened in the past 7 days. For example, participants might acknowledge guessing on an item such as “How often did you sit down to rest,” as this non-salient event is difficult to recall.

Response Options

The PROMIS response options (as of 9/26/05) are listed below. Several suggested questions are outlined. These questions can be addressed separately or within the context of reviewing particular items that use the scales.

GROUP 1 Never Rarely Sometimes Often Always	GROUP 2 Never Once a week or less Once every few days Once a day Every few hours	GROUP 3 A few minutes Several minutes to an hour Several hours A day or two More than 2 days	GROUP 4 None 1 day 2-3 days 4-5 days 6-7 days
GROUP 5 None Mild Moderate Severe Very Severe	GROUP 6 Not at all A little bit Somewhat Quite a bit Very much	GROUP 7 Without difficulty With some difficulty With much difficulty Unable to do	GROUP 8 Strongly disagree Disagree Agree Strongly Agree

- *Do you have any ideas about how to make these response groups better?*
- *Would you change any of the words used in any group?*
- *Looking at Group 1 (and 5, 6, 7, 8), how would you arrange these options from least to most serious/intense? Does this order make sense?*
- *How easy is it to tell the difference between each choice?*
- *Looking at Group 1, how do you distinguish “sometimes” from “often?” Is “often” more or less frequent than “sometimes?”*
- *Looking at Group 6, how do you distinguish “a little bit,” “somewhat,” and “quite a bit” from each other?*
- *Which group of responses is easiest to understand? Hardest to understand?*
- *Which group of responses do you prefer? Why?*
- *Are there enough choices within each group? Are there too many choices within a group?*
- *What came to mind when you read the word “severe?” “Very severe?”*

Response sets may need to be revised for a number of reasons including: (1) inconsistency in how participants would arrange responses in order of severity, (2) participants indicating that it is difficult to distinguish between choices, (3) participants indicating that there are not enough response options, (4) poor comprehension of words in response set, etc.

Item Review

Sample Pain Item

“During the past week, how severe has your pain been? None, Mild, Moderate, Severe, Very Severe.”

- *Can you say this question in your own words?*
- *What does “severe” mean to you?*
- *What exact days were you thinking about when you heard “past week”?*
From which day to which day? [example of integrating questions about response set into item probes]
- *How did you choose your answer? (For example, did you think about your pain at its worst, average your level of pain over the past 7 days, or consider how it has been compared to normal?)*
- *Was this question easy or hard to answer?*
- *Can you think of an easier way to word this question?*

Sample Physical Function Item:

(a) *“Are you able to climb several flights of stairs? Without difficulty, with some difficulty, with much difficulty, unable to do”*

- *Can you say this question in your own words?*
- *How did you choose your answer?*
- *How easy or hard was it to answer this question?*
- *How sure are you of your answer?*
- *Does this question apply to you?*

Determining whether or not an item needs revision based on participant feedback is subjective. Some situations requiring revision are relatively straight-forward. For example, if a participant interprets an item in a unique but understandable way, an item will need to be clarified to increase the likelihood of participants having a shared understanding of what the item is asking. Likewise, an item will need revision if one or more participants do not know the meaning of a word in the item or have a unique definition for a word. One should attend to items that patients identify as being difficult to answer or are very uncertain about their response. This could be due to the vocabulary used or syntax, but also because it is difficult to quantify the subjective experience in question.

Summary Questions:

- *Were you comfortable with all of these questions?*
- *Do you think most people will find these questions clear and easy to understand?*
- *Think about all the questions you answered on this form (item bank). When you think about [domain], are there any important questions we didn't ask you?*
- *Is there anything else, anything at all that you would like to suggest that would help us to improve these questions for future use?*

These are all the questions I have for you. Do you have any other comments about your experiences that you would like to share with me?

Your comments were very helpful. Thank you very much for your time.

APPENDIX C10: Standardized Debriefing Interview Guide For Substantially Revised Items

Standardized Debriefing Interview Guide for Substantially Revised Items

Introduction

Thank you for agreeing to give your feedback on questions about [domain]. I'm going to read you x number of questions, one at a time. I'd like you to answer the question. Then, we will talk about how you came up with your answer and how to make the question better. Here is the first item:

Read the revised item to the participant:

Over the last 7 days, I found it difficult to calm down: None of the time, a little of the time, some of the time, most of the time, all of the time.

Examples of probes:

Can you say this question in your own words?

Was this question easy or hard to answer?

How did you choose your answer?

What does "calm down" mean to you?

What exact days were you thinking about when you heard "last 7 days"? From which day to which day?

Now I'm going to read this question phrased in a different way. I'd like to know which version you prefer.

Read original item:

How often do you have any of the following experiences? How often during the past month did you find yourself having difficulty trying to calm down? Please use the scale: 1=always, 2=very often, 3=fairly often, 4=sometimes, 5=almost never, 6=never.

Examples of probes:

Which version do you prefer?

Which version do you find easier to understand?

Which version do you find easier to answer?

APPENDIX C11: Examples of “Substantially Revised” Items

Substantial Changes

GS1 (version 3): I feel distant from my friends

GS1 (version 4): I feel close to my friends

This is a reversal – seems quite substantial

GS5 (version 3) - Family communication about my illness is poor

GS5 (version 3) - I am satisfied with family communication about my illness

This is a reversal – seems quite substantial

GE2 (version 3): I am proud of how I am coping with my illness

GE2 (version 4): I am satisfied with how I am coping with my illness

Word substitution that is not a simplification

Not substantially revised

Adding or Removing Words

Hep 5 (original) – I have had a change in taste

Hep 5 (revised) – I have had a change in the way food tastes

Addition of words

N3 (original) – I worry about infections

N3 (revised) – I worry about getting infections

Addition of word

Hep 8 (original) – I have discomfort or pain in my stomach

Hep 8 (revised) – I have discomfort or pain in my stomach area

Addition of word for support/clarification

GS3 (version 3) I get support from my friends and neighbors

GS3 (version 4) I get support from my friends

Subtraction of word – I don't think this changes the overall meaning of the item and therefore is not substantial

Word Substitutions

Hep 1 (original) – I am embarrassed by a change in my appearance

Hep 1 (revised) - I am unhappy about a change in my appearance

Word sub – semantic simplification

Word Order

Hep 7 (original) – I have dry mouth

Hep 7 (revised) – My mouth is dry

Essentially a change in word order. Essentially semantic simplification

APPENDIX C12: Sample Cognitive Interview Data Summary

Example

1) Original form of item:

We are interested in your lifetime exercise patterns.

First, when you were 14 to 19 years old:

How many hours a week of brisk walking did you do?

How many hours a week of vigorous exercise such as running, cycling, swimming, or aerobics did you do?

How many hours a week of activities that required you to be on your feet (excluding running or walking) such as dancing, hiking, ... did you do?

2) Probes:

- a) Was this hard or easy to answer? (to determine comprehension and overall ability to read)
- b) How do you remember this? (to study recall strategy)
- c) How sure are you of your answer? (confidence probe)
- d) What, to you, is “vigorous exercise?” (comprehension/interpretation of a specific term)

3) Results

Subjects found it very difficult to remember back to the time period specified, at the required level of detail. In fact, it seemed that some subjects really could not even answer this with respect to their current behavior, let alone their behavior many years ago. Recall of information (assuming it was ever “learned” in the first place) seemed to be the dominant problem.

The cognitive interviewing staff needed to confer with the sponsor/client to clarify the question’s objectives. We were able to determine that use of a broad scale of level activity, comparing past and present behavior, would satisfy data objectives:

4) Suggested revision:

We are interested in your lifetime exercise patterns.

When you were 14 to 19 years old, were you more active than you are now, less active than now, or about as active as now?

**Example from Willis, GB (1999). Cognitive Interviewing: a “How To” Guide. Presented at the Meeting of the American Statistical Association.*