APPENDICES

Appendix A. Cognitive Interview Materials

- 1. Patient Interview Baseline
- 2. Patient Interview Assessment 2
- 3. Patient FAQ
- 4. Clinician Interview Baseline
- 5. Clinician Interview Assessment 2
- 6. Clinician FAQ
- 7. HEAL definitions

8.

| ID# | Initials | Date // |
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| | | |

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Please rate the following statements on a 5-point scale:

0 – Not at all 1 – A little bit 2 – Somewhat 3 – Quite a bit 4 – Very Much

| The Treatment Expectancy items are clear and easy to understand. | |
|--|--|
| The Treatment Expectancy items are relevant to my treatment experience. | |
| The Treatment Expectancy items provide useful information to my healthcare provider. | |
| The Patient-Provider Connection items are clear and easy to understand. | |
| The Patient-Provider Connection items are relevant to my treatment experience. | |
| The Patient-Provider Connection items provide useful information to my healthcare provider. | |
| The Healthcare Environment items are clear and easy to understand. | |
| The Healthcare Environment items are relevant to my treatment experience. | |
| The Healthcare Environment items provide useful information to my healthcare provider. | |
| The Positive Outlook items are clear and easy to understand. | |
| The Positive Outlook items are relevant to my treatment experience. | |
| The Positive Outlook items provide useful information to my healthcare provider. | |
| The Spirituality items are clear and easy to understand. | |
| The Spirituality items are relevant to my treatment experience. | |
| The Spirituality items provide useful information to my healthcare provider. | |
| The CAM Attitudes items are clear and easy to understand. | |
| The CAM Attitudes items are relevant to my treatment experience. | |
| The CAM Attitudes items provide useful information to my healthcare provider. | |
| The Pain Intensity items are clear and easy to understand. | |
| The Pain Intensity items are relevant to my treatment experience. | |
| | |

The **Pain Intensity** items provide useful information to my practitioner.

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Please rate the following statements on a 5-point scale:

0 – Not at all

1 – A little bit 2 – Somewhat 3 – Quite a bit 4 – Very Much

| The Pain Interference items are clear and easy to understand. | |
|---|--|
| The Pain Interference items are relevant to my treatment experience. | |
| The Pain Interference items provide useful information to my healthcare provider. | |
| The Limited Physical Function items are clear and easy to understand. | |
| The Limited Physical Function items are relevant to my treatment experience. | |
| The Limited Physical Function items provide useful information to my healthcare provider. | |
| The Sleep Problems items are clear and easy to understand. | |
| The Sleep Problems items are relevant to my treatment experience. | |
| The Sleep Problems items provide useful information to my healthcare provider. | |
| The Fatigue items are clear and easy to understand. | |
| The Fatigue items are relevant to my treatment experience. | |
| The Fatigue items provide useful information to my healthcare provider. | |
| The Depression items are clear and easy to understand. | |
| The Depression items are relevant to my treatment experience. | |
| The Depression items provide useful information to my healthcare provider. | |
| The Anxiety items are clear and easy to understand. | |
| The Anxiety items are relevant to my treatment experience. | |
| The Anxiety items provide useful information to my healthcare provider. | |

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For the following set of questions, we will be referring to the graph and item report resulting from the questions you were asked on the computer.

Did the questions on the computer assessment make sense?

What do you like/dislike about the graphical and numerical formats? What could we do to improve these formats?

Do the scores make sense? Do you understand from the graphs/item output which areas might be important to you and your provider?

Would this type of information help your treatment? In what way?

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How comfortable would you be discussing this information during your treatment sessions? How should the assessments be used in treatment? How useful do you think this information would be in communicating with your healthcare provider?

Do you like the color?

Are the HEAL definitions helpful?

Do you prefer paper-and-pencil questionnaires or computer questionnaires? Why?

Do you have any overall comments about your experience completing the questionnaires? What other suggestions do you have for us?

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For the following set of questions, we will be referring to the "Live Better with Pain Log"

Did this questionnaire make sense? Why or why not?

When you were making your ratings, did you refer to the pictures? Did the pictures accurately represent the questions? Would you change them in any way?

On a scale of 1-10, with 1 being not at all helpful and 10 being extremely helpful, how helpful were the pictures when you were answering the questions?

How helpful were the numbers below each set of pictures when you were making your ratings?

What questions or suggestions do you have about this assessment?

| D# | Initials | Date | // |
|------------------------------|--|-------------------------------|------|
| Please rate the followin | g statements on a 5-point scale: | | |
|) – Not at all | 1 – A little bit 2 – Somewhat | t 3 – Quite a bit 4 – Very | Much |
| The Treatment Exp | ectancy items are clear and easy to unders | stand. | |
| The Treatment Exp | ectancy items are relevant to my treatment | nt experience. | |
| The Treatment Exp | ectancy items provide useful information | to my healthcare provider. | |
| The Patient-Provide | er Connection items are clear and easy to | understand. | |
| The Patient-Provide | er Connection items are relevant to my tre | eatment experience. | |
| The Patient-Provide | er Connection items provide useful inform | nation to my healthcare provi | der. |
| The Healthcare Env | ironment items are clear and easy to und | erstand. | |
| The Healthcare Env | ironment items are relevant to my treatm | nent experience. | |
| The Healthcare Env | ironment items provide useful informatio | n to my healthcare provider. | |
| The Positive Outloc | k items are clear and easy to understand. | | |
| The Positive Outloc | k items are relevant to my treatment exp | erience. | |
| The Positive Outloc | k items provide useful information to my | healthcare provider. | |
| The Spirituality iter | ns are clear and easy to understand. | | |
| The Spirituality iter | ns are relevant to my treatment experienc | ce. | |
| The Spirituality iter | ns provide useful information to my health | hcare provider. | |
| The CAM Attitudes | items are clear and easy to understand. | | |
| The CAM Attitudes | items are relevant to my treatment exper | ience. | |
| The CAM Attitudes | items provide useful information to my he | ealthcare provider. | |
| The Pain Intensity i | tems are clear and easy to understand. | | |
| The Pain Intensity i | tems are relevant to my treatment experie | ence. | |
| The Pain Intensity i | tems provide useful information to my pra | actitioner. | |

PROMIS Patient Interview – Assessment 2

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| lot at all | 1 – A little bit | 2 – Somewhat | 3 – Quite a bit | 4 – Very Much |
|----------------------------|-----------------------------------|--------------------|-------------------|---------------|
| he Pain Interferen | ce items are clear and eas | sy to understand. | | |
| he Pain Interferen | ce items are relevant to m | ny treatment expe | erience. | |
| he Pain Interferen | ce items provide useful in | formation to my l | healthcare provid | er. |
| he Limited Physica | I Function items are clear | and easy to unde | erstand. | |
| he Limited Physica | I Function items are relev | vant to my treatm | ent experience. | |
| he Limited Physica | I Function items provide | useful information | n to my healthcar | e provider. |
| he Sleep Problems | items are clear and easy | to understand. | | |
| he Sleep Problems | items are relevant to my | treatment experi | ence. | |
| he Sleep Problems | items provide useful info | rmation to my he | althcare provider | |
| he Fatigue items an | e clear and easy to under | rstand. | | |
| he Fatigue items an | e relevant to my treatme | ent experience. | | |
| he Fatigue items pr | rovide useful information | to my healthcare | provider. | |
| he Depression item | ns are clear and easy to u | nderstand. | | |
| he Depression item | ns are relevant to my trea | tment experience | 2. | |
| he Depression iten | ns provide useful informa | tion to my health | care provider. | |
| he Anxiety items a | re clear and easy to unde | rstand. | | |
| he Anxiety items a | re relevant to my treatme | ent experience. | | |
| he Anxiety items p | rovide useful information | to my healthcare | e provider. | |

Initials__ .

PROMIS Patient Interview – Assessment 2

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PROMIS Patient Interview – Assessment 2

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| ID# | Initials . | Date | | |
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| | | | | |

For the following set of questions, we will be referring to the handouts titled "XXXXXXXX" (PROMIS/HEAL graph and items) and the questions you answered on the computer.

Did the questions on the computer assessment make sense?

Since taking the first assessment, have you and your treatment provider discussed the assessment or the results? If so, tell me more about that. Has the information been helpful?

Is it useful to see how your answers have changed over time? In what way?

What do you like/dislike about the graphical and numerical formats? What could we do to improve these formats?

Do you like the color?

| PROMIS Patient Interview – Assessment | 2 |
|--|---|
|--|---|

PCORI

| ID# | Initials | Date | _ // |
|---------|---|------------------------|----------------|
| Are the | HEAL definitions helpful? | | |
| | | | |
| Do you | understand that the presentation is over time? | | |
| | | | |
| | mfortable would you be discussing this information during yo nents be used in treatment? | ur treatment sessions? | How should the |
| | | | |
| | | | |
| What o | ther suggestions do you have for us? | | |
| | | | |
| | | | |
| | | | |

PCORI Interview FAQ's

<u>Patient:</u>

1. Can I have a hard copy of the graphs and items?

We would like the opportunity to speak with your healthcare provider before we give you a copy or your results. Once we have spoken with them, you are free to ask them for a copy of your results, or you can contact our office at (412) 246-6972. In order it give us a chance to reach your healthcare provider, we ask that you wait at least 30 days after this interview to contact us.

2. Can I have an electronic version (e.g. pdf) of the graphs and items?

Yes, we can provide you with a secured pdf after we have contacted your healthcare provider.

3. What does a rating of 50 mean?

A rating of 50 is considered "average" for the general population. These items were tested in a sample of the US population which was balanced for age, race, gender, and education.

The numbers on the graphs are percentiles on a scale of 0-100 that tell us the percent of people in general who rate this item less than you. For example, the 20th percentile is the value (or "rating") in which 20% of people score at or below.

4. Can you explain what the high ratings mean in the separate categories?

In general, higher ratings indicate "more" of that category, and vice versa. A higher rating could sometimes be more favorable, Patient Provider Connection, and sometimes less favorable, i.e. Pain Intensity.

5. Why are there only 4-6 questions in some of the categories?

All of the questions are presented in a Computerized Adaptive Test (CAT) format. Items are selected on the basis of the person's responses to previous items. Each person only needs to answer a subset of items to accurately estimate what would have been obtained by administering the entire set of items.

| 6. What are all of the possible response options? | | | | | | |
|---|--|--------------|-----------|-------------|---------------|--|
| For a majorit | For a majority of the questions, the possible responses are: <u>Frequency:</u> | | | | | |
| | Never | Rarely | Sometimes | Often | Almost Always | |
| | <u>Severity:</u> Not at all | A little bit | Somewhat | Quite a bit | Very Much | |

| Category | Response Options |
|-----------------------------|---|
| Treatment Expectancy | Not at all, A little bit, , Quite a bit, Very much |
| Patient-Provider Connection | Never, Rarely, , Often, Almost always |
| | Not at all, A little bit, , Quite a bit, Very much |
| Healthcare Environment | Never, Rarely,, Often, Almost always |
| | Not at all, A little bit, , Quite a bit, Very much |
| Positive Outlook | Never, Rarely, , Often, Almost always |
| | Not at all, A little bit, , Quite a bit, Very much |
| Spirituality | Never, Rarely, , Often, Almost always |
| | Not at all, A little bit, , Quite a bit, Very much |
| CAM Attitudes | Not at all, A little bit, , Quite a bit, Very much |
| Pain Intensity | Had no pain, Mild, , Severe, Very severe |
| | No pain, Mild, , Severe, Very severe |
| Pain Interference | Never, Rarely, , Often, Always |
| | Not at all, A little bit, , Quite a bit, Very much |
| Limited Physical Function | Cannot do, Quite a lot, , Very little, Not at all |
| | Can't do because of health, A lot of difficulty, , A little bit of difficulty, No difficulty at all |
| | Unable to do, With much difficulty, , With a little difficulty, |
| | Without any difficulty |
| Sleep Problems | Never, Rarely, , Often, Always |
| | Not at all, A little bit, , Quite a bit, Very much |
| | Very good, Good, , Poor, Very poor |
| Fatigue | Never, Rarely, , Often, Always |
| | Not at all, A little bit, , Quite a bit, Very much |
| | None, Mild, , Severe, Very severe |
| | None, 1 day, , 4-5 days, 6-7 days |
| Depression | Never, Rarely, , Often, Always |
| Anxiety | Never, Rarely, , Often, Always |

PCORI

| ID# Date // | |
|-------------|--|
|-------------|--|

Please rate the following statements on a 5-point scale:

0 – Not at all

1 – A little bit 2 – Somewhat 3 – Quite a bit 4 – Very Much

| The Treatment Expectancy items are clear and easy to understand. | |
|--|--|
| The Treatment Expectancy items are relevant to the care I provide. | |
| The Treatment Expectancy items provide useful information. | |
| The Patient-Provider Connection items are clear and easy to understand. | |
| The Patient-Provider Connection items are relevant to the care I provide. | |
| The Patient-Provider Connection items provide useful information. | |
| The Healthcare Environment items are clear and easy to understand. | |
| The Healthcare Environment items are relevant to the care I provide. | |
| The Healthcare Environment items provide useful information. | |
| The Positive Outlook items are clear and easy to understand. | |
| The Positive Outlook items are relevant to the care I provide. | |
| The Positive Outlook items provide useful information. | |
| The Spirituality items are clear and easy to understand. | |
| The Spirituality items are relevant to the care I provide. | |
| The Spirituality items provide useful information. | |
| The CAM Attitudes items are clear and easy to understand. | |
| The CAM Attitudes items are relevant to the care I provide. | |
| The CAM Attitudes items provide useful information. | |
| The Pain Intensity items are clear and easy to understand. | |
| The Pain Intensity items are relevant to the care I provide. | |
| The Pain Intensity items provide useful information. | |

| PROMIS | Clinician Interview | v – Base | line PCORI |
|----------------------------|--|----------------|-------------------------------|
| D# | Initials | | Date // |
| Please rate the following | g statements on a 5-point scale | 2: | |
|) – Not at all | 1 – A little bit 2 – | Somewhat | 3 – Quite a bit 4 – Very Much |
| The Pain Interferen | ce items are clear and easy to | understand. | |
| The Pain Interferen | ce items are relevant to the ca | re I provide. | |
| The Pain Interferen | ce items provide useful inform | ation. | |
| The Limited Physica | I Function items are clear and | easy to unde | erstand. |
| The Limited Physica | I Function items are relevant t | the care I p | provide. |
| The Limited Physica | I Function items provide usefu | Il information | n. |
| The Sleep Problems | items are clear and easy to ur | derstand. | |
| The Sleep Problems | items are relevant to the care | l provide. | |
| The Sleep Problems | items provide useful informat | ion. | |
| | | | |

The **Fatigue** items are clear and easy to understand.

The **Fatigue** items are relevant to the care I provide.

The **Fatigue** items provide useful information.

The **Depression** items are clear and easy to understand.

The **Depression** items are relevant to the care I provide.

The **Depression** items provide useful information.

The Anxiety items are clear and easy to understand.

The **Anxiety** items are relevant to the care I provide.

The Anxiety items provide useful information.

The Alcohol Use items are clear and easy to understand.

The **Alcohol Use** items are relevant to the care I provide.

The Alcohol Use items provide useful information.

PROMIS Clinician Interview – Baseline

PCORI

| ID# | Initials | Date | // | |
|-----|----------|------|----|--|
| | | | | |

For the following set of questions, we will be referring to the handouts titled "XXXXXXXX" (PROMIS/HEAL graph and items).

Are the questions your patient answered easy to understand? What would you change about them?

Would this type of information affect your treatment decisions? In what way?

What do you like/dislike about the graphical and numerical formats? What could we do to improve these formats?

How comfortable would you be discussing this information during your treatment sessions? How should the assessments be used in treatment?

| PROMIS | ine PCORI | |
|-------------------------|--|----------------|
| D# | Initials | Date / / |
| Do you prefer paper-an | d-pencil questionnaires or computer questio | onnaires? Why? |
| | | |
| | | |
| Vhat barriers are there | to implementing an assessment like this in y | your clinic? |
| | | |
| Vhat other suggestions | do you have for us? | |
| | | |
| | | |
| | | |

PROMIS Clinician Interview – Baseline

PCORI

| ID# | Initials | Date | / <u> </u> | |
|-----|----------|------|------------|--|
| | | | | |

For the following set of questions, we will be referring to the "Live Better with Pain Log"

Do you feel this questionnaire will be easily understood by patients? Why or why not?

Did the pictures accurately represent the questions? Would you change them in any way?

On a scale of 1-10, with 1 being not at all helpful and 10 being extremely helpful, how helpful is this information when formulating a treatment plan?

What questions or suggestions do you have about this assessment?

| Not at all | 1 – A little bit 2 – Somewhat 3 – Quite a bit 4 – Very Much |
|-------------------------------|---|
| The Treatment Expe | ectancy items are clear and easy to understand. |
| The Treatment Expe | ectancy items are relevant to the care I provide. |
| The Treatment Expe | ectancy items provide useful information. |
| The Patient-Provide | r Connection items are clear and easy to understand. |
| The Patient-Provide | r Connection items are relevant to the care I provide. |
| The Patient-Provide | r Connection items provide useful information. |
| The Healthcare Envi | ironment items are clear and easy to understand. |
| The Healthcare Envi | ironment items are relevant to the care I provide. |
| The Healthcare Envi | ironment items provide useful information. |
| The Positive Outloo k | k items are clear and easy to understand. |
| The Positive Outloo ł | k items are relevant to the care I provide. |
| The Positive Outloo k | k items provide useful information. |
| The Spirituality item | ns are clear and easy to understand. |
| The Spirituality item | ns are relevant to the care I provide. |
| The Spirituality item | ns provide useful information. |
| The CAM Attitudes i | items are clear and easy to understand. |
| The CAM Attitudes i | items are relevant to the care I provide. |
| The CAM Attitudes i | items provide useful information. |
| The Pain Intensity ite | ems are clear and easy to understand. |
| The Pain Intensity ite | ems are relevant to the care I provide. |
| The Pain Intensity ite | ems provide useful information. |

PROMIS Clinician Interview – Assessment2

ID# ____ ____

Please rate the following statements on a 5-point scale:

Initials__ .

PCORI

Date___ / ___ / ____

| Not at all | 1 – A little bit | 2 – Somewhat | 3 – Quite a bit | 4 – Very Much |
|----------------------------|------------------------------------|---------------------|-----------------|---------------|
| The Pain Interferen | ce items are clear and eas | sy to understand. | | |
| The Pain Interferen | ce items are relevant to th | ne care l provide. | | |
| The Pain Interferen | ce items provide useful in | formation. | | |
| The Limited Physica | I Function items are clear | and easy to unde | erstand. | |
| The Limited Physica | I Function items are relev | ant to the care I p | provide. | |
| The Limited Physica | I Function items provide | useful information | n. | |
| The Sleep Problems | items are clear and easy | to understand. | | |
| The Sleep Problems | items are relevant to the | care I provide. | | |
| The Sleep Problems | items provide useful info | rmation. | | |
| The Fatigue items a | re clear and easy to under | rstand. | | |
| The Fatigue items a | re relevant to the care I p | rovide. | | |
| The Fatigue items p | rovide useful information | • | | |
| The Depression iten | ns are clear and easy to u | nderstand. | | |
| The Depression iten | ns are relevant to the care | e I provide. | | |
| The Depression iten | ns provide useful informa | tion. | | |
| The Anxiety items a | re clear and easy to unde | rstand. | | |
| The Anxiety items a | re relevant to the care I p | rovide. | | |
| The Anxiety items p | | | | |

Initials__ .

PROMIS Clinician Interview – Assessment2

ID# _____

PCORI

Date___ / ___ / ____

| PROMIS | Clinician | Interview - | Assessment2 |
|--------|-----------|-------------|-------------|
|--------|-----------|-------------|-------------|

| ID# | Initials | Date / | / | |
|-----|----------|--------|---|--|
| | | | | |

For the following set of questions, we will be referring to the handouts titled "XXXXXXXX" (PROMIS/HEAL graph and items).

Are the questions your patient answered easy to understand? What would you change about them?

Have you discussed the results of the first assessment with this patient? What affect has that had on your treatment plan?

What do you like/dislike about the graphical and numerical formats? What could we do to improve these formats?

How comfortable would you be discussing this information during your treatment sessions? How should the assessments be used in treatment?

| PROMIS Clinician Interview – Assessment 2 PCOR | | |
|--|--|----------------|
| ID# | Initials | Date // |
| Is it useful to see how y | our patient's answers have changed over time | ? In what way? |
| | | |
| | | |
| What barriers are there | to implementing an assessment like this in you | ur clinic? |
| | | |
| What other suggestions | do you have for us? | |
| | | |
| | | |
| | | |

PCORI Interview FAQ's (Healthcare provider)

1. Can I make these items a part of my patient's medical record/clinical file?

****NO.** Please do not add hard copies or electronic copies of these data into your patient's files. If you would like to document a discussion of the information, we suggest a general "as reported by [patient]..." approach, rather than stating the information was directly drawn from the computerized assessment study.

As a part of our NIH Certificate of Confidentiality, we are not permitted to include references or documents related to this study in the patients' medical records. Also, the current study is a pilot study and the graphs and formatting will be changing throughout the study.

2. Can I have a hard copy of the graphs and items?

Yes, we will provide you with a hard copy of each. Feel free to provide your patient with a copy as well. (The patient has seen this info during his/her baseline interview, but was not provided a copy at that point.)

3. Can I have an electronic version (e.g. pdf) of the graphs and items?

Yes, we can provide you with a secured pdf.

4. What does a score of 50 mean?

A score of 50 is considered "average" for the general population.

These items were tested in a sample of the US population which was balanced for age, race, gender, and education.

5. What do scores between 40 and 60 mean?

A score of 40 or 60 means that 40 or 60% of the population scored at the same level or below your patient.

6. Can you explain what the high scores mean in the separate categories?

In general, higher scores indicate "more" of that category, and vice versa. Certain categories are more "negative" while others could be considered "positive". For example, a higher than average score in the Anger category would indicate "more" anger. On the other hand, a higher than average score in Social Satisfaction would indicate "more" satisfaction.

7. Do you have definitions of each of the categories?

Yes, we have definitions available for most of the categories if you are interested. They are also available on the main PROMIS website: <u>http://www.nihpromis.org/measures/domainframework</u>

8. Why are there only 4-6 questions in some of the categories?

All of the questions are presented in a Computerized Adaptive Test (CAT) format. CAT is a method of administering tests by computer, based on the psychometric framework of IRT (Item Response Theory). Items are selected on the basis of the examinee's responses to previously administered items. This process uses an algorithm to estimate person "ability" and then chooses the best next item, enabling test administration based on specifications such as content coverage and test length. The capacity to rank all examinees on the same continuum, <u>even if they have not been given any common items</u>, allows for a test that is individually tailored to each examinee. With item banking, each patient need only answer a subset of items to obtain a measure that accurately estimates what would have been obtained by administering the entire set of items.

Helpful Definitions

Treatment Expectancy

• Your expectations about whether the treatment will be helpful

Patient-Provider Connection

• Your views of your relationship with your healthcare provider

Healthcare Environment

• Your views about the healthcare provider's office and staff

Positive Outlook

• Your level of confidence and optimism, in general

Spirituality

• Your spiritual beliefs and experience of spiritual support

Attitudes toward CAM (Complementary Alternative Medicine)

• Your views about integrative medicine or CAM