Introduction

This document describes resources for measuring sexual function and satisfaction using the PROMIS© system. **Section 1** of this manual presents a brief, comprehensive measure of sexual function for men and women, known as the PROMIS Sexual Function and Satisfaction Measures Brief Profile. For many users, this short measure (8 items for males, 10 items for females) will suffice.
Section 2 of this manual is intended for users who might want to create a more customized assessment of sexual function. Parts of the second section require the reader to have greater sophistication in measurement methodology.

SECTION 1: The PROMIS Sexual Function and Satisfaction Measures Brief Profile

Overview

The PROMIS Sexual Function and Satisfaction Measures Brief Profile (PSxFBP) provides scores on 7 different subdomains of sexual function: Interest in Sexual Activity, Vaginal Discomfort (women only), Lubrication (women only), Erectile Function (men only), Orgasm, and Global Satisfaction with Sex Life (see below for subdomain definitions). The PSxFBP is intended for broad use, although almost all of the development work was with cancer populations. (Research is ongoing to expand development beyond cancer.) The PSxFBP is available for men and women and consists of the best items selected from each subdomain for general purposes. Each question asks respondents to report on their experiences over the past 30 days.

Availability

PDF versions of the male and female PSxFBP are available for download on the Assessment Center℠ website (http://assessmentcenter.net/). Alternatively, the PSxFBP can be administered electronically by creating a study within Assessment Center℠ and selecting the PSxFBP as one of the study measures. Also, a version of this document which contains a list of items and their response scores can be accessed from within the Assessment Center application via the PDF link in the upper right hand corner of the application. Please review the Appendices section to determine which version you are currently accessing.

Subdomain Definitions

Global Satisfaction with Sex Life is the person's overall evaluation of his or her sex life. No limitation is placed on what the person includes in his or her definition of "sex life." Higher scores indicate more satisfaction with sex life. Lower scores indicate less satisfaction with sex life.

Interest in Sexual Activity refers to a conscious awareness of wanting to engage in sexual activity. Items are gender-neutral. Higher scores indicate more interest. Lower scores indicate less interest.

Lubrication refers to the wetness or dryness of the vagina during sexual activity. Higher scores indicate more lubrication. Lower scores indicate less lubrication.

Vaginal Discomfort refers to the degree of physical discomfort of the vagina during and immediately following sexual activity. Higher scores indicate more discomfort as reflected by pain and/or uncomfortable tightness. Lower scores indicate less discomfort as indicated by no pain, bleeding, and/or uncomfortable tightness.

Erectile Function refers to the ability to achieve and maintain an erection for sexual activity. Higher scores indicate better function. Lower scores indicate poorer function.

Orgasm assesses the degree to which the person has experienced a satisfying climax. It is measured with a single, gender-neutral item for which higher scores indicate a greater ability to have satisfying orgasms, and lower scores indicate less ability.

> ***Note**:* Additional subdomains not included in the PSxFBP are Interfering Factors, Therapeutic Aids, Sexual Activities, and Anal Discomfort. See Section 2 for definitions.

Reliability and Validity

A detailed account of the development of the PROMIS© Sexual Function domain, including reliability and validity data, is found in Section 2. Correlations between the PSxFBP and corresponding subdomains of two well-established measures—the FSFI and the IIEF—ranged between .48 and .92 (see Table 3). The subdomains of the PSxFBP discriminate between people who had and had not asked an oncology provider about sexual problems (Table 4). Test-retest correlations are > .65 for all subdomains of the PSxFBP (see Table 5).

Scoring

PROMIS instruments are scored using item-level calibrations. This means that the most accurate way to score a PROMIS instrument is to utilize scoring tools within Assessment Center or API that look at responses to each item for each participant. Data collected in either of these platforms will automatically score in this way. We refer to this as "response pattern scoring." Response pattern scoring can be used when data was collected on paper or in another software package through the Assessment Center Scoring Service. Because response pattern scoring is more accurate than the use of raw score/scale score look up tables, it is preferred. However, if you aren't able to use response pattern scoring, you can use the instructions below which rely on raw score/scale score look-up tables.

With the exception of the Orgasm subdomain, all subdomain scores are expressed as *T* scores (mean = 50, standard deviation = 10). At present, a *T* score of 50 corresponds to the mean response among the cancer survivors used for item testing (total *N* = 819). If the PSxFBP is administered electronically using Assessment Center™, scoring is done automatically by the software and scores for every subdomain are added as new variables.

Multiple Domains

The score metric for PROMIS instruments is Item Response Theory (IRT), a family of statistical models that link individual questions to a presumed underlying trait or concept represented by all items in the item bank. In the case of the PROMIS Sexual Function and Satisfaction Brief Profile, the instrument is made up of six individual short forms that are scored individually: Interest in Sexual Activity, Vaginal Discomfort (women only), Lubrication (women only), Erectile Function (men only), Orgasm, and Global Satisfaction with Sex Life. Scoring uses item-level calibrations. This means that the most accurate way to score a PROMIS Profile is to utilize scoring tools within Assessment Center that look at responses to each item for each participant. We refer to this as "response pattern scoring." Response pattern scoring tools within Assessment Center can be used even if data was collected on paper or in another software package. Because response pattern scoring is more accurate than the use of raw score/scale score look up tables, it is preferred. However, if you aren't able to use response pattern scoring, you can use the instructions below which rely on raw score/scale score look-up tables (see tables in Appendix A).

Not Applicable Responses

Each question has multiple response options ranging in value from one to four or five. In many cases, there is also a response option that allows a respondent to report a "not applicable" response. For example, for Erectile Function, a respondent can answer "have not tried to get an erection in the past 30 days." These "not

applicable" responses cannot be used to calculate a score. They can only be used as individual items to describe respondents.

Create a Summed Raw Score

A raw summed score is created for each domain in the profile. However, this raw summed domain score can only be created if ALL items from that domain were answered *and* NO "not applicable" responses were given. For example, if a respondent only answered one of the two Global Satisfaction with Sex Life items, a valid Global Satisfaction with Sex Life score cannot be produced. If a different respondent answered both of these items, but endorsed "Have not had sexual activity in the past 30 days" for one or both items, a valid Global Satisfaction with Sex Life score cannot be produced.

After confirming all items in a given domain were answered without endorsing a "not applicable" response (identified by a score of 0), add up the response scores to all items in that domain. This is the raw summed score for that domain. For example, for Global Satisfaction with Sex Life, the raw summed score can range from 2 (endorsed "Not at all" to both items) to 10 (endorsed "Very" or "Very much" to both items).

Note that for the single Orgasm item, no summed score is produced. This item is not scored using Item Response Theory. Instead, raw responses can be used in analyses.

Use the Raw Score/T-Score Look-up Tables

Locate the applicable score conversion table in Appendix A and use this table to translate the domain raw summed score into a T-score for each participant. The T-score rescales the raw score into a standardized score with a mean of 50 and a standard deviation (SD) of 10. Therefore a person with a T-score of 40 is one SD below the mean. The standardized T-score is reported as the final score for each participant for each domain.
For the Global Satisfaction with Sex Life domain, a raw summed score of 6 converts to a T-score of 48.15 with a standard error (SE) of 3.52 (see scoring table in Appendix A). Thus, the 95% confidence interval around the observed score ranges from 41.25 to 55.04 (T-score $\pm$ (1.96*SE) or 48.15 $\pm$ (1.96*3.52).

SECTION 2: Creation of a Customized Sexual Function and Satisfaction Assessment

Introduction

Section 1 was intended to help researchers who are content to use a brief "off the shelf" profile measure of sexual function and satisfaction—the PSxFBP. Section 2 provides information necessary for those users who wish to select specific subdomains and/or specific items within subdomains to create a customized assessment of sexual function and satisfaction using the PROMIS system. Section 2 also provides more detailed information concerning the development, reliability, and validity of the PROMIS SexFS.

Instrument Descriptions

Through the PROMIS Cancer Supplement, instruments assessing multiple components of sexual functioning were developed. Together, these instruments are known as the PROMIS Sexual Function and satisfaction measure (PROMIS SexFS). Some instruments are gender specific. Most items are not specific to cancer, but have thus far only been validated in cancer populations. (Research is ongoing to expand development of the PROMIS SexFS instruments beyond cancer.) The PROMIS SexFS uses a 30-day recall period. Where possible, items use response options common to other PROMIS banks. Some PROMIS SexFS instruments include items from other sexual function instruments, such as the Female Sexual Function Index and the UCLA Prostate Cancer Index.

Available Instruments

PROMIS has 11 sexual function and satisfaction instruments. Five of these instruments are calibrated item banks (e.g. PROMIS Bank v1.0 - Global Satisfaction w Sex Life). This means that if one or more items from within that instrument are administered, a respondent's score will be calculated using item response theory statistics. If these instruments are administered outside of Assessment Center you may rely on raw score/scale score look-up tables to determine scores (see tables in Appendix B).

Six of the instruments do not have calibrated items (e.g. PROMIS Pool v1.0 - Sexual Activities). This means that items within those instruments are not combined in any way to create a score. Each item in these instruments measures a very specific construct corresponding only to that item (e.g., how much radiation burns have affected one's satisfaction with their sex life). For any given item in these uncalibrated instruments, the researcher can use the raw item responses directly for analyses. The available instruments are listed in Table 1.

Instrument Name	# of items	Calibrated or Uncalibrated
Global Satisfaction with Sex Life	7	Calibrated
Interest in Sexual Activity	4	Calibrated
Lubrication	8	Calibrated
Vaginal Discomfort	10	Calibrated
Erectile Function	8	Calibrated
Orgasm	3	Uncalibrated
Interfering Factors	10	Uncalibrated
Therapeutic Aids	9	Uncalibrated
Sexual Activities	12	Uncalibrated
Anal Discomfort	5	Uncalibrated
Sexual Function Screener Items	3	Uncalibrated

Table 1: PROMIS Sexual Function and Satisfaction Instruments

Subdomain Definitions

Definitions for those subdomains measured by the PSxFBP (Global Satisfaction with Sex Life, Interest in Sexual Activity, Lubrication, Vaginal Discomfort, Erectile Function, and Orgasm) are found in Section 1. Definitions for the remaining 5 subdomains are below.

Interfering Factors is a collection of items each of which assesses the person's perception of the degree to which various factors affect satisfaction with sex life. These factors include symptoms of disease and side effects from treatment and other issues that have been identified by patients. These items are intended to be "stand alone" items and do not comprise a unidimensional scale. Some items are gender-specific.

Therapeutic Aids is a collection of items each of which assesses the use of hormones, personal lubrications, medications, or devices intended to allow for or improve sexual function. These items are intended to be "stand alone" items and do not comprise a unidimensional scale.

Sexual Activities is a collection of items each of which assesses the frequency of engaging in specific intimate or sexual behaviors either alone or with a partner. These items are intended to be "stand alone" items and do not comprise a unidimensional scale. Some items are gender-specific.

Anal Discomfort is an evaluation of anal irritation, pain, or bleeding during or after anal sex. Items are only asked of people who indicate in the activities subdomain they have had anal sex in the past 30 days. There have not been enough data collected to do psychometric evaluation of these items.

Sexual Function Screener Items ask about sex (gender), whether people are in a relationship that could involve sexual activity, and whether they have had any type of sexual activity with a partner in the past 30 days.

In addition, there are male-specific items related to the Orgasm subdomain that ask about timing of ejaculation and pain or burning during or after ejaculation. These can be administered and scored as single items.

Selecting Appropriate Items

All items in the PROMIS SexFS were not intended to be administered together. Researchers should select the sexual function and satisfaction items that are relevant to their specific sample. Some examples are provided.
Example 1: A study proposes to compare three treatment approaches for early stage cervical cancer: surgery alone, surgery and radiation, and radiation alone. In addition to disease control, cancer treatment comorbidities are being compared, including sexual function outcomes. The researchers want to measure key domains of function, including overall sexual satisfaction, interest, vaginal irritation or pain, orgasm, and lubrication. They are also interested in which side effects from treatments affect participants' sex lives, as each of the treatment modalities carries different potential changes in sexual function; surgery usually results in a foreshortened vaginal canal and radiation may cause vaginal mucosal thinning, vaginal adhesions, decreased lubrication and vaginal stenosis. The 10-item **PSxFBP** for women can be used to assess sexual function broadly and distinguish between sexual side effects associated with treatment modality, and can be used to help patients make informed treatment decisions. Additional items on surgical scars, pain, and fatigue from the **Interfering Factors** instrument can help the researchers determine which side effects affect satisfaction with sex life for their participants. Finally, the researchers include the items for women that assess use of **Therapeutic Aids** to determine whether using personal lubricants or hormones modifies sexual satisfaction or function.

Example 2: A study designed to promote compliance with SSRI antidepressants proposes to assess whether sexual function contributes to non-compliance. Patients prescribed fluoxetine are longitudinally followed with monthly assessments of sexual function and frequency of sexual activities in order to determine the relationship between sexual dysfunction and non-compliance. The researchers have room for about 20 items on sexual function, so they choose to use the **PSxFBP** for men (8-items) and women (10-items) to gauge function plus the 12 items from the **Sexual Activities** subdomain. Thus, for all participants in the study, sexual activities, interest in sexual activity, orgasm, and global satisfaction with sex life are assessed. For women, lubrication and vaginal discomfort are also assessed, and for men, erectile function is also assessed.

Example 3: A study of soy-derived estrogen is tested to determine if it improves sexual function among menopausal women self-identified as having hyposexual desire. The researchers choose to administer all items from the **Interest in Sexual Activity** instrument, since sexual desire is their main outcome of interest. They also administer the **PSxFBP** for women to assess satisfaction with sex life, lubrication, vaginal discomfort, and orgasm.

A Note on Response Options for Sexual Activities

Most sexual activity items are available using two different sets of responses. Items identified with an "a" in their Item ID use the response options 1=Have not done in the past 30 days, 2=Once, 3=Two to three times, 4=Four to five times, 5=Six or more times. Items identified with a "b" in their Item ID use the response options 1=Have not done in the past 30 days, 2=Once a week or less, 3=Once every few days, 4=Once a day, 5=More than once a day. As you can see, the "a" response options reflect less activity. This set of response options is likely most appropriate for individuals for whom you expect reduced sexual activity (e.g., cancer patients receiving chemotherapy). The "b" response options reflect higher levels of sexual activity. This set of response options would be most appropriate for individuals you expect to have higher levels of sexual activity (e.g., healthy individuals). Investigators should carefully consider their purpose in recording sexual activities and select response options that are most appropriate. It is possible that the "a" and "b" options available here are not the best for a particular research setting. Investigators might also consider whether a daily sexual activity log could be used in place of these items, which require a 30-day recall period.

Procedures and Data in Support of Validity and Reliability

Face Validity. Face validity is established when subject matter experts agree that the scale appears to measure its intended focus. Face validity for the PROMIS SexFS scales was established with a review by expert panels within and external to the PROMIS SexFS committee; all experts concurred that the items within the scales appeared to measure sex function.

Content Validity. Content validity refers to how well the scale assesses all aspects of the construct being measured. Establishing the content validity of PROMIS instruments began with patient input to assure that the subdomains and their items corresponded to reported patient experiences, and with a review by expert panels to assure that the selected theoretical constructs corresponded to the scientific literature. Using a consensus-driven approach, the PROMIS SexFS committee conducted a literature search for articles published from 1991 through 2007, yielding 257 articles that reported the administration of a psychometrically evaluated sexual function measure to individuals diagnosed with cancer. With few exceptions, the 31 identified measures had not been widely tested in cancer populations (Jeffery et al., 2009). We collated available items from the measures and created preliminary domain definitions. Each item was then subjected to detailed review to eliminate repetition within bins ("winnowing") and to develop uniform recall periods and response categories. After qualitative expert item review, 47 extant items were selected for further testing. Concurrently, we conducted 16 focus groups with 109 cancer patients (Flynn et al., 2010). These groups explored the impact of cancer and its treatments on sexual experience to determine whether domain definitions and the identified items reflected patients' personal experiences. Separate focus groups were held for patients in active treatment for breast, prostate, lung, colorectal, gynecological, and other (mixed) cancers and for survivors after treatment for breast, prostate, gynecological, and other cancer types. We developed a matrix of themes and groups, which was double-coded (inter-rater reliability was over 90%). As a check on the data we received from the patient focus groups, we conducted 2 clinician focus groups to assess the clinical relevance of the proposed conceptual model and obtain clinicians' views of how cancer and its treatment affected patients' sexual health. New items were created to address conceptual gaps identified by the focus group participants. With updated items in hand, we conducted cognitive interviews with patients (n=39) (Fortune-Greeley et al., 2009). Each item was seen by at least 5 patients, at least 1 of whom was not white and at least 2 of whom had less than a 9th grade reading level. 87 items were passed through to the next phase. We convened 7 experts on sexual function and cancer to review this work to date.

The item-testing phase consisted of large-scale data collection (n=819; 388 males, 430 females, 1 person did not specify sex) and administration of the items in national and local samples through the NexCura Internet Panel, the Duke University tumor registry, and the Duke oncology clinics. (Appendix C shows patient characteristics, including the distribution of cancer types.) We also added targeted recruitment of additional lesbian, gay, and bisexual cancer patients and survivors through online communities. Psychometric analysis of the items followed established PROMIS methodology (Reeve et al., 2007) and resulted in 11 instruments: 5 calibrated and 6 uncalibrated. A summary of fit statistics are shown in Table 2.

Instrument Name	CFI	TLI	RMSEA
Global Satisfaction with Sex Life	0.983	0.976	0.168
Interest in Sexual Activity	0.998	0.995	0.129
Lubrication	0.985	0.979	0.187
Vaginal Discomfort	0.993	0.991	0.124
Erectile Function	0.988	0.986	0.134

CFI: comparative fit index
TLI: Tuker-Lewis index
RMSEA: root-mean-square error of approximation

Table 2: Fit Indices for Confirmatory Factor Analysis of Calibrated Subdomains.

Construct Validity. Construct validity refers to how well scores on the measure are related to other variables that, for theoretical reasons, ought to be related to the measure in question. Construct validity of the PROMIS SexFS has been assessed in two ways.

First, we used data from the 819 patients with cancer (see above) to examine the correlations between subdomains of the PROMIS SexFS and other measures of similar constructs. These are displayed in Table 3. In general, these correlations provide strong evidence for the construct validity of the PROMIS SexFS.

Women (N = 430)		**Men** (N = 388)	
Measures	r*	Measures	r*
PROMIS Interest in Sexual Activity	0.84 (0.82)	PROMIS Interest in Sexual Activity	0.82 (0.79)
FSFI† Desire		IIEF‡ Desire	
FSFI Arousal	0.71 (0.68)		
PROMIS Lubrication	0.92 (0.9)	PROMIS Erectile Function	0.81 (0.69)
FSFI Lubrication		IIEF Erectile Function	
PROMIS Vaginal Discomfort	0.9 (0.84)		
FSFI Pain			
PROMIS Orgasm	0.78 (0.78)	PROMIS Orgasm	0.62 (0.62)
FSFI Orgasm		IIEF Orgasmic Function	
PROMIS Global Satisfaction with Sex Life	0.76 (0.62)	PROMIS Global Satisfaction with Sex Life	0.82 (0.66)
FSFI Satisfaction		IIEF Overall Satisfaction	
		IIEF Intercourse Satisfaction	0.75 (0.68)

Note : Correlations in parentheses are for the PROMIS Sexual Function Brief Profile scores.
*Pearson correlation coefficients
†Female Sexual Function Index
‡International Index of Erectile Function

Table 3: Correlations between PROMIS Sexual Function and Satisfaction Subdomains and Corresponding Measures.

Second, we examined whether scores on selected subdomains of the PROMIS SexFS could discriminate between groups that should, in theory, differ in terms of their sexual experiences. During item testing, participants were also asked whether they had ever asked an oncology professional about sexual problems. We hypothesized that asking for help with sexual problems may indicate a clinically meaningful decrement in function. As Table 4 shows, those who had asked for help had significantly greater interest in sexual activity and increased vaginal discomfort and lower levels of erectile function, lubrication, orgasm, and overall satisfaction. Furthermore, the differences were as high as three-quarters of a standard deviation. These effect sizes were greater than or equal to the effects for the corresponding subscales of the FSFI and IIEF. In three cases, the PROMIS SexFS and PSxFBP detected statistically significant ($p<.05$) differences between those who did and did not ask, whereas the FSFI or IIEF did not.

Reliability. Two types of reliability data are available at this time for the PROMIS SexFS. First, estimates of internal consistency (Cronbach's alpha) were computed for all calibrated banks. They are displayed in Table 4. All indicate excellent internal consistency. Second, test-retest reliability was examined in a sample of 202 participants (101 male, 101 female), about half of whom had some chronic disease. Participants completed the PROMIS SexFS twice with one month between test administrations. Intraclass correlation coefficients between the two administrations are shown in Table 5, ranging from .71 - .87.

PROMIS Sexual Function and Satisfaction Measure			PROMIS SexFS Brief Profile		Legacy Measures		
Domain	Effect Size	p-value[b]	Effect Size	p-value[b]	Domain	Effect Size	p-value[b]
Interest in Sexual Activity (women)	0.18	0.16	0.16	0.19	FSFI Desire	-0.05	0.69
					FSFI Arousal	-0.13	0.35
Interest in Sexual Activity (men)	0.22	0.04	0.21	0.05	IIEF Desire	0.14	0.2
Erectile Function	-0.45	<.0001	-0.49	<.0001	IIEF Erectile Function	-0.22	0.04
Lubrication	-0.75	<.0001	-0.66	<.0001	FSFI Lubrication	-0.67	<.0001
Vaginal Discomfort	0.75	<.0001	0.6	<.0001	FSFI Pain	-0.6	<.0001
Orgasm (women)	-0.4	<.0001	-0.4	0.003	FSFI Orgasm	-0.11	0.41
Orgasm (men)	-0.55	<.0001	-0.55	<.0001	IIEF Orgasmic Function	-0.55	<.0001
Global Satisfaction with Sex Life (women)	-0.24	0.05	-0.27	0.03	FSFI Satisfaction	0.08	0.54
Global Satisfaction with Sex Life (men)	-0.15	0.15	-0.18	0.09	IIEF Overall Satisfaction	-0.16	0.14

Abbreviations: PROMIS Patient Reported Outcomes Measurement Information System; FSFI Female Sexual Function Index; IIEF International Index of Erectile Function

a: Difference in the means between people who answered "Yes" (N = 237) and "No" (N = 569) to the question, "Have you ever asked an oncology doctor or nurse about problems with your sex life?" divided by the common standard deviation.

b: From t-test comparing PROMIS measure to legacy measure.

Table 4: Effect Sizes Discriminating Askers From Non-Askers[a] (N=806).

	Women		Men	
Measures	Cronbach's alpha (N = 430)	ICC PROMIS SxeFS (PSxFBP) (N = 101)	Cronbach's alpha (n = 388)	ICC PROMIS SxeFS (PSxFBP) (N = 101)
PROMIS Interest in Sexual Activity	0.89	0.77 (0.72)	0.87	0.71 (0.65)*
PROMIS Lubrication	0.95	0.87 (0.87)		
PROMIS Vaginal Discomfort	0.94	0.80 (0.75)		
PROMIS Erectile Function			0.92	0.87 (0.77)
PROMIS Global Satisfaction with Sex Life	0.93	0.75 (0.69)	0.92	0.74 (0.66)
*Numbers reflect the deletion of a single outlier with a "5" at first administration and a "1" at second administration. Inclusion of the outlier results in ICCs of 0.55 and 0.54 for the full bank and PSxFBP, respectively.				

Table 5: Reliability of Calibrated Subdomains.

Procedures for Selecting the PROMIS Sexual Function and Satisfaction Profile in Assessment Center

The PROMIS Sexual Function and Satisfaction Profile is a publicly available instrument in the Assessment Center library. Assessment Center allows you to create a study-specific data collection website for capturing participant data. There are three versions of the Profile within Assessment Center: a male version, a female version and a combined gender version which is appropriate for males and females. The combined gender version will branch the respondent to the appropriate questions (erectile function versus lubrication and vaginal discomfort) based on gender.

Before using an existing PROMIS Sexual Function and Satisfaction instrument, or creating a custom one, you must first create a study. To do this, select the Studies tab and click on the Create New Study button. Enter study information and click on the Save button. Select the Studies tab and the new study should appear in the My Studies box. To add a PROMIS Sexual Function and Satisfaction Profile to your study in Assessment Center first, navigate to the Study Content page by clicking the Instruments tab. Next, click the Add button to access the Add an Instrument page. From this page, you can search for sexual function and satisfaction instruments by using the search drop lists at the top of the page. Once you have identified the appropriate PROMIS Sexual Function and Satisfaction Profile instrument, check the box next to the desired instrument, and click Add to Study button at the top or bottom of the search results box. Additional information about using Assessment Center is available in the Assessment Center User Manual (available at assessmentcenter.net) or within the application through Help (upper right corner hyperlink).

Procedures for Creating a Custom PROMIS Sexual Function and Satisfaction Instrument in Assessment Center

Assessment Center allows you to create a custom instrument so you may individually select sexual function and satisfaction items of interest to administer to participants. To do this, navigate to the Study Content page by

clicking the Instruments tab. Click on the Create button. Enter instrument information on the Instrument Properties page selecting Short Form for Instrument Type. Click Save to be navigated back to the Study Content page. Next, click on your newly created instrument's name which will appear as a hyperlink to be navigated to the Instrument Details page. Then click on the Find Items button to access the Add an Item page. From this page, you can search for sexual function and satisfaction instruments by using the search drop lists at the top of the page. Once you have identified the appropriate PROMIS Sexual Function and satisfaction instrument (e.g., Therapeutic Aids), click on the plus sign to the left of the instrument name. The page will expand to display all items within the instrument. Check the box next to the desired items and click Add to Instrument at the top or bottom of the search results box. To view your custom instrument with the items you have just selected, click on the Instruments tab. Next click the plus sign to the left of the instrument name.

Procedures for Previewing PROMIS Studies in Assessment Center

Before launching a study, Assessment Center allows you to first preview the study. To preview your study you must first click on the Team hyperlink to the right of the desired study. Next identify the study team members. Assign roles to individual members by highlighting their name and checking the box next to the desired role (*Note: the team member launching the study preview must have the role of Study Administrator or Instrument/Item Administrator)*. Next select the Preview tab. Click on the Preview Study button (*Note: the preview may take a few seconds to launch)*. Next click on the Continue button and follow instructions on the study Welcome page.

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Contact Us

For more information about PROMIS, contact us at info@nihpromis.org. For more information about accessing the PROMIS Sexual Function instruments or administering them through Assessment Center, contact help@assessmentcenter.net or 877-283-0596.

References

DeWalt, D., Rothrock, N., Yount, S., Stone, A. A., & on behalf of the PROMIS cooperative group. (2007). Evaluation of item candidates: the PROMIS qualitative item review. *Medical Care, 45(5),* S12-21.

Fortune-Greeley, A. K., Flynn, K. E., Jeffery, D. D., Williams, M. S., Keefe, F. J., Reeve, B. B., Willis, G. B., & Weinfurt, K. P. (2009). Using cognitive interviews to evaluate items for measuring sexual functioning across cancer populations: improvements and remaining challenges. *Quality of Life Research, 18(8)*, 1085-93.

Jeffery, D. D., Tzeng, J. P., Keefe, F.J., Porter, L. S., Hahn, E. A., Flynn, K. E., Reeve, B. B., & Weinfurt, K. P. (2009). Initial report of the cancer Patient-Reported Outcomes Measurement Information System (PROMIS) sexual function committee: Review of sexual function measures and domains used in oncology. *Cancer, 115(6)*, 1142-53.

Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S, Amtmann D, Bode R, Buysse D, Choi S, Cook K, DeVeillis R, DeWalt D, Fries JF, Gershon R, Hahn EA, Lai JS, Pilkonis P, Revicki D, Rose M, Weinfurt K, Hays R. (2010). The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol*. *63(11),* 1179-84.

Flynn, K. E., Jeffery, D. D., Keefe, F. J., Porter, L. S., Shelby, R. A., Fawzy, M. R., Gosselin, T. K., Reeve, B. B., & Weinfurt, K. P. (2011). Sexual functioning along the cancer continuum: focus group results from the Patient-Reported Outcomes Measurement Information System (PROMIS). *Psycho-Oncology, 20(4),* 378-86.

Flynn K.E., Reese J.B., Jeffery D.D., Abernethy A.P., Lin L., Shelby R.A., Porter L.S., Dombeck C.B., Weinfurt K.P. (in press). Patient experiences with communication about sex during and after treatment for cancer. *Psycho-Oncology*.

Flynn K.E., Jeffery D.D., Reeve B.B., Lin L., Wilder Smith A., Abernethy A.P., Reese J.B., Weinfurt K.P. "Progress on the PROMIS® Sexual Function Measure." Poster presented at the International Society for Quality of Life Research Annual Conference; October 29, 2010; London, England.

Weinfurt, K. "Improving the Measurement of Sexual Outcomes in Cancer: The NIH PROMIS Approach." Center for Outcomes and Policy Research, Dana-Farber Cancer Institute, Boston, Massachusetts, May 17, 2011

Flynn K.E., Weinfurt K.P. "Development and Validation of the PROMIS Sexual Function Measure." Presentation at the Duke Translational Medicine Institute Annual Research Career Day; May 20, 2011; Durham, NC, USA.

Flynn K.E. "Assessing Sexual Health in Cancer Survivors." Presentation at the Cancer Survivorship and Sexual Health Symposium sponsored by the International Society for Sexual Medicine and the Sexual Medicine Society of North America; Washington, DC, USA; June 18, 2011.

Weinfurt K.P., Lin L., Broderick J.E., Dombeck C.B., Fawzy, M.R., Snyder D.C., Williams M.S., Flynn K.E. "Validity of 1-month Recall for Components of Sexual Function." To be presented as a poster at the International Society for Quality of Life Research Annual Conference; October 28, 2011; Denver, Colorado, USA.

Flynn K.E., Lin L., Dombeck C., Fawzy M., Abernethy A.P., Bruner D.W., Reese J.B., Reeve B.B., Smith A.W., Weinfurt K.P. "Validating the PROMIS® Sexual Function Brief Profile Measures." To be presented at the International Society for Quality of Life Research Annual Conference; October 29, 2011; Denver, Colorado, USA.

Weinfurt K.P., Lin L., Broderick J.E., Dombeck C.B., Fawzy, M.R., Snyder D.C., Williams M.S., Flynn K.E. “Mood and Gender Effects on the Accuracy of 30-day Recall of Sexual Function.” To be presented at the International Society for Quality of Life Research Annual Conference; October 29, 2011; Denver, Colorado, USA.

Appendix A - Sexual Function and Satisfaction Measures Brief Profile Look-up Tables

Global Satisfaction with Sex Life *Score Conversion Table*		
Raw Score	T Score	SE*
2	30.67	4.86
3	36.8	3.84
4	40.94	3.59
5	44.76	3.6
6	48.15	3.52
7	51.5	3.57
8	55.11	3.54
9	58.98	3.76
10	65.6	5.23

*SE=Standard Error on T-score metric

Interest in Sexual Activity *Score Conversion Table*		
Raw Score	T Score	SE*
2	33.42	4.72
3	40.01	2.82
4	43.64	2.69
5	47.46	2.82
6	51.16	2.8
7	54.86	2.85
8	58.96	2.87
9	63.28	3.06
10	69.97	4.37

*SE=Standard Error on T-score metric

Lubrication *Score Conversion Table*		
Raw Score	T Score	SE*
2	37.05	5.45
3	43.58	3.26
4	46.25	3.07
5	48.5	2.99
6	50.64	2.96
7	52.84	2.98
8	55.3	3.06
9	58.55	3.38
10	64.82	5.24

*SE=Standard Error on T-score metric

Vaginal Discomfort *Score Conversion Table*		
Raw Score	T Score	SE*
3	34.34	5.3
4	41.13	3.56
5	45.4	2.83
6	48.09	2.69
7	50.51	2.61
8	52.62	2.61
9	54.55	2.63
10	56.5	2.69
11	58.56	2.78
12	61.03	2.99
13	64.32	3.42
14	69.81	4.96

*SE=Standard Error on T-score metric

Erectile Function *Score Conversion Table*		
Raw Score	T Score	SE*
3	36.84	5.41
4	42.81	3.22
5	44.88	3.05
6	46.76	2.82
7	48.44	2.65
8	49.99	2.58
9	51.51	2.58
10	53.08	2.6
11	54.78	2.64
12	56.64	2.66
13	58.69	2.72
14	61.32	2.96
15	67.25	4.67

*SE=Standard Error on T-score metric

Appendix B - Sexual Function and Satisfaction Bank Look-up Tables

Vaginal Discomfort

Score Conversion Table

Raw Score	T Score	SE*
10	33.20	5.05
11	38.71	3.26
12	41.09	2.98
13	42.68	2.67
14	44.01	2.43
15	45.13	2.19
16	46.11	2.01
17	46.96	1.91
18	47.74	1.86
19	48.47	1.83
20	49.16	1.80
21	49.83	1.78
22	50.48	1.77
23	51.12	1.77
24	51.74	1.77
25	52.35	1.77
26	52.96	1.77
27	53.56	1.79
28	54.17	1.79
29	54.77	1.80
30	55.38	1.81
31	56.00	1.84
32	56.63	1.86
33	57.28	1.89
34	57.95	1.93
35	58.66	2.00
36	59.40	2.08
37	60.20	2.17
38	61.04	2.28
39	61.93	2.41
40	62.87	2.55
41	63.88	2.70
42	64.96	2.88
43	66.14	3.09
44	67.42	3.29
45	68.89	3.57
46	70.34	3.74
47	72.36	4.09
48	74.03	4.31
49	77.08	4.90

*SE= Standard Error on T-score

Lubrication

Score Conversion Table

Raw Score	T Score	SE*
8	30.99	4.74
9	35.47	3.16
10	37.54	2.72
11	38.97	2.48
12	40.14	2.27
13	41.16	2.10
14	42.06	1.98
15	42.89	1.90
16	43.66	1.85
17	44.40	1.80
18	45.09	1.78
19	45.78	1.77
20	46.45	1.77
21	47.12	1.76
22	47.78	1.77
23	48.46	1.79
24	49.14	1.80
25	49.84	1.81
26	50.54	1.82
27	51.26	1.84
28	51.99	1.86
29	52.74	1.87
30	53.52	1.88
31	54.32	1.90
32	55.16	1.92
33	56.05	1.96
34	57.01	2.01
35	58.06	2.10
36	59.26	2.25
37	60.67	2.50
38	62.38	2.82
39	64.78	3.33
40	69.26	4.85

*SE= Standard Error on T-score

Erectile Function

Score Conversion Table

Raw Score	T Score	SE*
8	30.72	5.42
9	33.94	5.38
10	32.59	5.62
11	34.48	5.35
12	34.19	5.18
13	38.05	3.83
14	39.75	3.72
15	40.68	3.90
16	42.28	3.16
17	43.57	2.86
18	44.65	2.69
19	45.66	2.55
20	46.59	2.45
21	47.46	2.38
22	48.30	2.33
23	49.11	2.30
24	49.89	2.29
25	50.68	2.29
26	51.46	2.30
27	52.26	2.32
28	53.08	2.37
29	53.93	2.42
30	54.83	2.50
31	55.79	2.62
32	56.80	2.71
33	57.94	2.92
34	59.27	3.29
35	61.08	4.00
36	62.12	3.75
37	64.00	3.67
38	68.47	4.76

*SE= Standard Error on T-score

Global Satisfaction with Sex Life

Score Conversion Table

Raw Score	T Score	SE*
7	29.59	4.56
8	34.45	3.10
9	37.14	2.73
10	39.16	2.54
11	40.77	2.42
12	42.15	2.33
13	43.40	2.26
14	44.55	2.21
15	45.63	2.18
16	46.66	2.16
17	47.66	2.16
18	48.63	2.16
19	49.60	2.16
20	50.56	2.17
21	51.53	2.18
22	52.51	2.18
23	53.49	2.18
24	54.49	2.18
25	55.49	2.17
26	56.51	2.17
27	57.54	2.18
28	58.61	2.20
29	59.73	2.23
30	60.93	2.31
31	62.25	2.43
32	63.74	2.60
33	65.54	2.90
34	67.85	3.33
35	72.01	4.63

*SE= Standard Error on T-score

Interest in Sexual Activity

Score Conversion Table

Raw Score	T Score	SE*
4	32.03	4.78
5	37.01	3.41
6	40.15	2.94
7	42.55	2.73
8	44.67	2.74
9	46.79	2.80
10	48.87	2.81
11	50.86	2.78
12	52.85	2.79
13	55.15	2.84
14	57.58	2.81
15	59.78	2.83
16	62.19	2.94
17	64.98	3.07
18	68.43	3.36
19	71.76	3.92
20	76.17	4.87

*SE= Standard Error on T-score

Appendix C. Characteristics of Validation Sample (N=819)

Characteristic	Total (N = 819)
Age, mean ± SD, y	58.5 ± 11.8
Age group, No. (%)	
≤ 40 years	59 (7)
41 to 50 years	127 (16)
51 to 64 years	377 (46)
65 to 79 years	232 (28)
≥ 80 years	21 (3)
Race, No. (%)	
Black or African American	80 (10)
American Indian/Alaska Native	10 (1)
Asian	12 (1)
Native Hawaiian/Other Pacific Islander	10 (1)
White	705 (87)
Multiple races or other	2 (< 1)
Hispanic or Latino ethnicity, No. (%)	21 (3)
Educational attainment, No. (%)	
Less than high school	21 (3)
High school graduate/GED	100 (12)
Some college	255(31)
College degree	229 (28)
Advanced degree (MA, PhD, MD)	211 (26)
Treatment status in past month, No. (%)	
None (ie, posttreatment follow-up)	526 (64)
Undergoing treatment	290 (36)
Radiation therapy	29 (10)
Hormonal therapy (eg, tamoxifen, anastrozole, leuprolide)	140 (48)
Chemotherapy (injection or oral)	116 (40)
Immunotherapy (eg, interferon)	9 (3)
Other	36 (12)
Recurrence of cancer, No. (%)	151 (18)
Cancer spread to lymph nodes, No. (%)	202 (25)
Cancer spread to another area, No. (%)	134 (16)
Primary cancer diagnosis, No. (%)	
Bone/muscle cancer	14 (2)
Brain cancer	4 (< 1)
Breast cancer	252 (35)
Colorectal	98(13)
Esophageal or stomach cancer	17 (2)
Gynecologic cancer	29 (4)
Head/neck cancer	9 (< 1)
Hodgkin lymphoma	23 (3)
Leukemia	20 (3)
Liver cancer	3 (< 1)
Lung cancer	56 (8)
Melanoma	4 (< 1)
Multiple Myeloma	2 (< 1)
Non-Hodgkin lymphoma	12 (2)
Pancreatic cancer	5 (< 1)
Prostate cancer	146 (20)
Urologic cancer	23 (3)