

# SEXUAL FUNCTION AND SATISFACTION MEASURE DIFFERENCES

A brief guide to differences between the PROMIS® Sexual Function and Satisfaction instruments:

ADULT
PROMIS Pool v2.0 – Sexual Function and Satisfaction: Anal Discomfort with Sexual Activity
PROMIS Pool v2.0 – Sexual Function and Satisfaction: Bother Regarding Sexual Function (Female)
PROMIS Pool v2.0 – Sexual Function and Satisfaction: Bother Regarding Sexual Function (Male)
PROMIS Pool v2.0 – Sexual Function and Satisfaction: Factors Interfering with Sexual Satisfaction
PROMIS Pool v2.0 – Sexual Function and Satisfaction: Screeners
PROMIS Pool v2.0 – Sexual Function and Satisfaction: Sexual Activities (Female)
PROMIS Pool v2.0 – Sexual Function and Satisfaction: Sexual Activities (Male)
PROMIS Pool v2.0 – Sexual Function and Satisfaction: Therapeutic Aids for Sexual Activity (Female)
PROMIS Pool v2.0 – Sexual Function and Satisfaction: Therapeutic Aids for Sexual Activity (Male)
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Erectile Function
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Interest in Sexual Activity
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Oral Discomfort with Sexual Activity
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Oral Dryness with Sexual Activity
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Orgasm – Ability
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Orgasm – Pleasure
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Satisfaction with Sex Life
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Vaginal Discomfort with Sexual Activity
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Vaginal Lubrication for Sexual Activity
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Vulvar Discomfort with Sexual Activity - Clitoral
PROMIS Scale v2.0 – Sexual Function and Satisfaction: Vulvar Discomfort with Sexual Activity - Labial
PROMIS Sexual Function and Satisfaction v2.0 Brief Profile (Female)
PROMIS Sexual Function and Satisfaction v2.0 Brief Profile (Male)
PROMIS Sexual Function and Satisfaction v2.0 Full Profile (Female)
PROMIS Sexual Function and Satisfaction v2.0 Full Profile (Male)
PROMIS Bank v1.0 – Sexual Function and Satisfaction: Global Satisfaction with Sex Life*
PROMIS Bank v1.0 – Sexual Function and Satisfaction: Interest in Sexual Activity*
PROMIS Bank v1.0 – Sexual Function and Satisfaction: Lubrication*
PROMIS Bank v1.0 – Sexual Function and Satisfaction: Vaginal Discomfort*
PROMIS Bank v1.0 – Sexual Function and Satisfaction: Erectile Function*
PROMIS Pool v1.0 – Sexual Function and Satisfaction: Orgasm*
PROMIS Pool v1.0 – Sexual Function and Satisfaction: Interfering Factors*
PROMIS Pool v1.0 – Sexual Function and Satisfaction: Therapeutic Aids*
PROMIS Pool v1.0 – Sexual Function and Satisfaction: Sexual Activities*
PROMIS Pool v1.0 – Sexual Function and Satisfaction: Anal Discomfort*
PROMIS Pool v1.0 – Sexual Function and Satisfaction: Screener Items*
PROMIS Sexual Function Profile v1.0 (Female)*
PROMIS Sexual Function Profile v1.0 (Male)*
PROMIS Sexual Function Profile v1.0 (Male and Female)*

\*Retired measure

## INTRODUCTION

This document describes resources for the multiple versions of PROMIS I Function and Satisfaction instruments. It is divided into two sections: the first section is for v2.0 instruments and the second section is for v1.0 instruments.

# SECTION 1: SEXUAL FUNCTION AND SATISFACTION (SexFS) VERSION 2.0

This section provides information on the PROMIS® SexFS v2.0 domains (Table 1) and profile measures (Table 2).

<b>Table 1. PROMIS SexFS v2.0 Domains</b>	<b># of items</b>	<b>Calibrated or Uncalibrated<sup>a</sup></b>	<b>Scored<sup>b</sup></b>	<b>Requires Activity Screener?<sup>c</sup></b>
Satisfaction with Sex Life	5	Calibrated	Scored	Yes
Vaginal Lubrication for Sexual Activity	6	Calibrated	Scored	Yes
Vaginal Discomfort with Sexual Activity	11	Calibrated	Scored	Yes
Erectile Function	11	Calibrated	Scored	Yes
Vulvar Discomfort with Sexual Activity – Labial	4	Calibrated	Scored	Yes
Vulvar Discomfort with Sexual Activity – Clitoral	4	Calibrated	Scored	Yes
Oral Discomfort with Sexual Activity	6	Calibrated	Scored	Yes
Oral Dryness with Sexual Activity	3	Calibrated	Scored	Yes
Orgasm – Pleasure	3	Calibrated	Scored	Yes
Orgasm – Ability	1	Uncalibrated	Scored	Yes
Interest in Sexual Activity	2	Uncalibrated	Scored	No
Bother Regarding Sexual Function	11	Uncalibrated	Unscored	No
Factors Interfering with Sexual Satisfaction	35	Uncalibrated	Unscored	No
Therapeutic Aids for Sexual Activity	7	Uncalibrated	Unscored	No
Sexual Activities	15	Uncalibrated	Unscored	No
Anal Discomfort with Sexual Activity	6	Uncalibrated	Scored	Yes
Sexual Function Screener Items	5	Screener	Unscored	No

<sup>a</sup>Refers to whether the domain consists of IRT-calibrated items or not. <sup>b</sup>Indicates whether T-scores centered around U.S. population means are available. <sup>c</sup>Indicates whether domain is only intended for sexual active adults.

## INTRODUCTORY VIDEO

**Table 2. PROMIS SexFS v2.0 Profiles**

	Full Profile Items (#)		Brief Profile Items (#)	
	Sexual activity in past 30 days	No sexual activity in past 30 days	Sexual activity in past 30 days	No sexual activity in past 30 days
Interest in Sexual Activity	2	2	2	2
Sexual Activity Screener	1	1	1	1
Reasons for No Sexual Activity	--	1	--	1
Erectile Function (men)	3	--	2	--
Lubrication (women)	3	--	2	--
Vaginal Discomfort (women)	2	--	2	--
Labial Discomfort (women)	2	--	1	--
Clitoral Discomfort (women)	2	--	1	--
Orgasm Ability	1	--	1	--
Orgasm Pleasure	2	--	1	--
Satisfaction with Sex Life	4	--	2	--
Oral Discomfort	2	--	--	--
Oral Dryness	2	--	--	--
Anal Discomfort	2	--	--	--
Total # of Items (Men)	19	4	9	4
Total # of Domains/scores (Men)	8	1	5	1
Total # of Items (Women)	25	4	13	4
Total # of Domains/scores (Women)	11	1	8	1

An introductory video about the PROMIS SexFS v2.0 can be found here:

[https://www.youtube.com/watch?v=CQwo\\_2GlaJA](https://www.youtube.com/watch?v=CQwo_2GlaJA)

## SEXUAL FUNCTION AND SATISFACTION DOMAINS

The PROMIS SexFS v2.0 measures a range of sexual activities, symptoms, functioning, and evaluation of experiences over the past 30 days. Also included are general screener items that ask about sexual activity in the past 30 days and reasons for not having sexual activity. The SexFS v2.0 measures are universal rather than disease-specific. The SexFS v2.0 includes the following domains:

**Screener Items** ask about sexual activity in the past 30 days and reasons for not having sexual activity.

**Interest in Sexual Activity** assesses a conscious awareness of wanting to engage in sexual activity during the past 30 days. Items are gender-nonspecific. Higher scores indicate greater interest.

**Satisfaction with Sex Life** assesses how satisfying and pleasurable the person regards his or her sexual life in the past 30 days with no limitation on how the person defines “sex life.” Items are gender-nonspecific. Higher scores indicate more satisfying sexual activities.

**Orgasm – Ability** assesses the ease with which a person has been able to have an orgasm over the past 30 days. It is measured with a single, gender-nonspecific item for which higher scores indicate a greater ability to have an orgasm.

**Orgasm – Pleasure** assesses how pleasurable or satisfying the person's orgasms have felt in the past 30 days. Items are gender-nonspecific. Higher scores indicate more pleasurable orgasms.

**Erectile Function** assesses the frequency and quality of achieving and maintaining an erection for sexual activity over the past 30 days. Higher scores indicate better function.

**Vaginal Discomfort with Sexual Activity** assesses physical discomfort of the vagina during and immediately following sexual activity, including sensations of pain, rubbing, burning, pulling, or ripping experienced over the past 30 days. Higher scores indicate greater discomfort.

**Vulvar Discomfort with Sexual Activity – Clitoral** assesses the degree of physical discomfort, including pain, of the clitoris experienced with sexual activity in the past 30 days. Higher scores indicate greater discomfort.

**Vulvar Discomfort with Sexual Activity – Labial** assesses the degree of physical discomfort, including pain, of the labia experienced with sexual activity in the past 30 days. Higher scores indicate greater discomfort.

**Vaginal Lubrication for Sexual Activity** scale assesses the wetness or dryness of the vagina experienced for sexual activity over the past 30 days. Higher scores indicate greater lubrication. These items are intended to assess the lubrication of the vagina without the assistance of personal lubricant products. As a result, it is recommended that respondents be instructed to select item responses in accordance with their natural vaginal lubrication only and to disregard the additive effects of personal lubricants.

**Anal Discomfort with Sexual Activity** assesses physical discomfort, irritation, pain, and/or bleeding around the anus or rectum during or after sexual activity over the past 30 days. Items are gender-nonspecific.

**Oral Discomfort with Sexual Activity** assesses the degree of physical discomfort in the mouth, including pain and/or irritation, experienced with sexual activity in the past 30 days. Items are gender-nonspecific. Higher scores indicate greater discomfort.

**Oral Dryness with Sexual Activity** assesses the lack of saliva in the mouth experienced with sexual activity in the past 30 days. Items are gender-nonspecific. Higher scores indicate greater dryness.

**Factors Interfering with Sexual Satisfaction** is a collection of items, each of which assesses the person's perception of the degree to which various factors affected their satisfaction with sex life in the past 30 days. These factors include symptoms of disease, side effects from treatment, and other experiences that have been identified by patients. Some items are gender-nonspecific. These items are intended to be stand-alone items and do not comprise a unidimensional scale.

**Therapeutic Aids for Sexual Activity** is a collection of items, each of which assesses the use in the past 30 days of hormones, personal lubrications, medications, or devices intended to allow for or improve sexual function. Some items are gender-nonspecific. 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 affectionate or sexual behaviors either alone or with a partner in the past 30 days. Some items are gender-nonspecific. These items are intended to be "stand-alone" items and do not comprise a unidimensional scale.

**Bother Regarding Sexual Function** is a collection of items, each of which assesses the degree of bother people report for each specific aspect of sexual functioning in the past 30 days. Some items are gender-nonspecific. These items are intended to be "stand-alone" items and do not comprise a unidimensional scale.

## INTRODUCTION TO ASSESSMENT OPTIONS

All items in the PROMIS SexFS were not intended to be administered together, as some domains might not be relevant for particular situations and reliable scores can be generated without having to administer all of the items in a domain. Researchers should select the sexual function and satisfaction domains and items that are

relevant to their specific sample. There are multiple assessment options: the full profile, brief profile, and customized short forms of any individual domain (that is, a selection of items from the desired domain). When administering any of these options, instruct participants to answer all of the items (i.e., questions or statements) presented. Tables 1 and 2 show how many items are in each individual domain and profile. Any of these options can be administered on paper or by computer.

Whether one uses a customized short form or profile, for those domains marked “calibrated,” the score metric is derived from Item Response Theory (IRT), a family of statistical models that link individual questions to a presumed underlying trait or concept within the overall domain of sexual function, represented by items in the item banks. When choosing among the options available, it is useful to consider the precision gained with longer instruments versus the psychological, physical, and cognitive burden placed on respondents as a result of the number of questions asked.

## **INSTRUMENT DIFFERENCES**

Tables 1 and 2 provide a helpful overview of the different instruments and assessment options. To summarize the tables, of the PROMIS SexFS instruments, 9 are calibrated scales. 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. Three of the instruments are scored but not calibrated. The items within those instruments are combined to create a score, but this score is not based on item response theory statistics. Five of the instruments do not have calibrated items and are not scored, that is, 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.

### **Profiles**

Profiles are of collections of short forms and items that assess a person with respect to multiple aspects of sexual function and satisfaction. The SexFS currently includes Brief Profiles and Full Profiles (see below). Items were selected for inclusion based on rankings using psychometric and pragmatic criteria: (1) maximum interval information (where applicable, i.e., IRT information curves reflected the greatest degree of precision for the greatest range of the latent variable of interest), (2) consistent item formatting, and (3) content coverage.

### **Brief Profiles (Male, Female)**

The Brief Profiles—one for males, one for females—efficiently assess interest in sexual activity followed by a screener item about sexual activity. For those who have not been sexually active in the past 30 days, a fourth and final question asks about reasons for not having sexual activity. For those who have been sexually active in the past 30 days, men are asked about erectile function, while women are asked about vaginal lubrication, vaginal discomfort, and vulvar discomfort; men and women are asked about orgasm and satisfaction with sex life. These are the domains that are most likely relevant for the majority of healthy people and those suffering from chronic diseases.

### **Full Profiles (Male, Female)**

The Full Profiles—one for males, one for females—includes all of the domains measured in the Brief Profiles, but also adds oral dryness, oral discomfort, and anal discomfort. For the domains that overlap between the Brief and Full Profiles, the Full Profiles use equal or greater number of items to assess each domain.

## Customized Short Forms

Within any of the 9 calibrated scales, users can select one or more items to create a customized short form for measuring that domain. Selection of the items could be based on suitability of the item for the particular population of interest. Note that the items that generally perform the best from the 9 calibrated scales are found on the Brief Profiles and Full Profiles (see above).

In selecting among assessment options, the differences are domain coverage and instrument length. If you are working with a sample in which you want the most precise measure, use a longer short form. If you have little room for additional measures but really wanted to capture something as a secondary outcome, use a shorter instrument (e.g., brief profile or just 1 or 2 domains of interest).

## PREVIEW OF SAMPLE ITEM

Below is an excerpt from the paper version of the Brief Profile (Female). This is the paper version format used for all profile instruments. It is important to note that automatic scoring is not available for paper administration.

SFSAT101r	<b>In the past 30 days</b> , how satisfied have you been with your sex life?
	<input type="checkbox"/> <sub>1</sub> Not at all
	<input type="checkbox"/> <sub>2</sub> A little bit
	<input type="checkbox"/> <sub>3</sub> Somewhat
	<input type="checkbox"/> <sub>4</sub> Quite a bit
	<input type="checkbox"/> <sub>5</sub> Very
SFSAT102r	<b>In the past 30 days</b> , how much pleasure has your sex life given you?
	<input type="checkbox"/> <sub>1</sub> None
	<input type="checkbox"/> <sub>2</sub> A little bit
	<input type="checkbox"/> <sub>3</sub> Some
	<input type="checkbox"/> <sub>4</sub> Quite a bit
	<input type="checkbox"/> <sub>5</sub> A lot

## VERSION DIFFERENCES

Some PROMIS domains have multiple versions of instruments (i.e., v1.0, v1.1, v2.0). Generally, **it is recommended that you use the most recent version available which can be identified as the instrument with the highest version number.**

Building on v1.0 of the PROMIS Sexual Function and Satisfaction measure (SexFS), a comprehensive development process was undertaken to create an expanded and improved PROMIS SexFS v2.0. This tool assesses multiple components of sexual functioning, and the validation process included a strong focus on inclusiveness with regard to literacy level, race, age, sexual orientation, and health conditions. Note that while v1.0 was developed exclusively in cancer patients, v2.0 retains the content validity for cancer patients and expands on it, making v2.0 a better measure for cancer populations than v1.0. Scores from v1.0 measures should not be compared to scores from v2.0 measures. Those who have administered items from the SexFS v1.0 and wish to use v2.0 scoring should contact the developers for more information.

Several features of SexFS v2.0 are consistent with v1.0. The measurement system is modular and customizable in that users need only measure those sexual function domains of relevance to their particular study or sample. One important change from v1.0 to 2.0 is that scores are now expressed using a meaningful metric, with scores centered around norms for the population of sexually active US adults. Norms are provided herein for age and sex to aid in the interpretation of SexFS scores. Also, differential item functioning (DIF) was examined by gender,

sexual activity, and age to assess the appropriateness of items across different groups of people. Finally, the v2.0 domains demonstrated good convergent and known groups validity and reliability. The final set of items is applicable for both men and women, those sexually active with a partner and without, and those who identify as heterosexual or straight, lesbian, gay, or bisexual.

## SECTION 2: THE PROMIS SEXUAL FUNCTION AND SATISFACTION MEASURES V1.0

### INTRODUCTION

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 measures v1.0 (PROMIS SexFS). Some instruments are gender specific. Most items are not specific to cancer, but had only been validated in cancer populations at the time of their publication. The PROMIS SexFS uses a 30-day recall period. Where possible, items use response options common to other PROMIS instruments. Some PROMIS SexFS instruments include items from other sexual function instruments, such as the Female Sexual Function Index and the UCLA Prostate Cancer Index. Table 3 includes a list of the available PROMIS SexFS v1.0 domains.

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 3: PROMIS Sexual Function and Satisfaction v1.0 Instruments

### V1.0 DOMAIN 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. These items are intended to assess the lubrication of the vagina without the assistance of personal lubricant products. As a result, it is recommended that respondents be instructed to select item responses in accordance with their natural vaginal lubrication only and to disregard the additive effects of personal lubricants.



**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 includes a gender-neutral item for which higher scores indicate a greater ability to have satisfying orgasms, and lower scores indicate less ability. It also includes male-specific items that ask about timing of ejaculation and pain or burning during or after ejaculation. These can be administered and scored as single items.

**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.

## INTRODUCTION TO ASSESSMENT OPTIONS

PROMIS has 11 sexual function and satisfaction v1.0 instruments (see Table 3). All items in the PROMIS SexFS were not intended to be administered together, as some domains might not be relevant for particular situations and reliable scores can be generated without having to administer all of the items in a domain. Researchers should select the sexual function and satisfaction domains and items that are relevant to their specific sample.

There are multiple assessment options: the [brief profile](#) and [customized short forms](#) of any individual domain (that is, a selection of items from the desired domain). When administering any of these options, instruct participants to answer all of the items (i.e., questions or statements) presented. Table 3 shows how many items are in each individual domain. Either option can be administered on paper or by computer.

Whether one uses a customized short form or profile, for those domains marked "calibrated," the score metric is derived from Item Response Theory (IRT), a family of statistical models that link individual questions to a presumed underlying trait or concept within the overall domain of sexual function, represented by items in the item banks. When choosing among the options available, it is useful to consider the precision gained with longer

instruments versus the psychological, physical, and cognitive burden placed on respondents as a result of the number of questions asked.

## **INSTRUMENT DIFFERENCES**

Five of the SexFS v1.0 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 electronic scoring you may rely on raw score/scale score look-up tables to determine scores (see PROMIS Sexual Function and Satisfaction Scoring Manual).

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.

### **PROMIS Sexual Function and Satisfaction Brief Profile v1.0**

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. 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.

### **Customized Short Forms**

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 FOR SEXFS V1.0**

**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 9<sup>th</sup> 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 A 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 4.

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: Tucker-Lewis index			
RMSEA: root-mean-square error of approximation			

Table 4: Fit Indices for Confirmatory Factor Analysis of Calibrated Domains (v1.0).

**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 5. 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	PROMIS Interest in Sexual Activity	0.82
FSFI <sup>†</sup> Desire	(0.82)	IIEF <sup>‡</sup> Desire	(0.79)
FSFI Arousal	0.71		
	(0.68)		
PROMIS Lubrication	0.92	PROMIS Erectile Function	0.81
FSFI Lubrication	(0.9)	IIEF Erectile Function	(0.69)
PROMIS Vaginal Discomfort	0.9		
FSFI Pain	(0.84)		
PROMIS Orgasm	0.78	PROMIS Orgasm	0.62
FSFI Orgasm	(0.78)	IIEF Orgasmic Function	(0.62)
PROMIS Global Satisfaction with Sex Life	0.76	PROMIS Global Satisfaction with Sex Life	0.82
FSFI Satisfaction	(0.62)	IIEF Overall Satisfaction	(0.66)
		IIEF Intercourse Satisfaction	0.75
			(0.68)
<p>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</p>			

Table 5: Correlations between PROMIS Sexual Function and Satisfaction v1.0 Domains 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 6 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 7.

PROMIS Sexual Function and Satisfaction Measure			PROMIS SexFS Brief Profile		Legacy Measures		
Domain	Effect Size	p-value <sup>b</sup>	Effect Size	p-value <sup>b</sup>	Domain	Effect Size	p-value <sup>b</sup>
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 6: Effect Sizes Discriminating Askers From Non-Askers<sup>a</sup> (N=806); v1.0).**

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 7, ranging from .71 - .87.

Measures	Women		Men	
	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 7: Reliability of Calibrated v1.0 Domains.

The following experts generously provided helpful input to the PROMIS sexual function and satisfaction domain working group:

	<u>Sexual Function and Satisfaction Domain Group</u> (including NIH)	<u>Duke Clinical Research Institute CCGE staff</u>	<u>Duke University School of Nursing</u>
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## CONTACT US

For more information about PROMIS, accessing the PROMIS Sexual Function instruments or administering them, contact us at [help@healthmeasures.net](mailto:help@healthmeasures.net).

## FREQUENTLY ASKED QUESTIONS (FAQs)

Q: I am interested in learning more. Where can I do that?

Review the HealthMeasures website at [www.healthmeasures.net](http://www.healthmeasures.net).

Q: Is the SexFS appropriate for LGBT populations?

Self-identified lesbian, gay, and bisexual individuals were engaged in the development process in focus groups, cognitive interviews, and item testing, and item wording is generally appropriate regardless of sexual orientation. However, transgender participants were not a particular focus for the v1.0 or v2.0 measure validation efforts; additional work will be needed to demonstrate validity for transgender participants.

Q: I'm worried that patients might be too embarrassed or offended to answer some of these questions. What has been the experience of PROMIS with this measure?

In testing v1.0 of this measure in a large population of patients with cancer, there were no more missing data on the sexual function measure than other measures on different topics that were being tested simultaneously (e.g., sleep quality, cognitive function, and illness impact). Since then, v2.0 was tested in additional populations and settings and missing data have not been a significant problem. Skipped items can be minimized by informing study participants at the outset that your study will be asking about different domains of health that are important to understand, including (for example) physical function, sleep, sexual function, and fatigue.

Q: Are these instruments available in other languages?

Yes! Look at the HealthMeasures website (<http://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis/available-translations>) or current information on PROMIS translations.

Q: Can I make my own short form?

Yes, custom short forms can be made by selecting any items from an item bank. This can be scored using the Scoring Service ([https://www.assessmentcenter.net/ac\\_scoring-service](https://www.assessmentcenter.net/ac_scoring-service)).

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## **Appendix A. Characteristics of Validation Sample**

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)