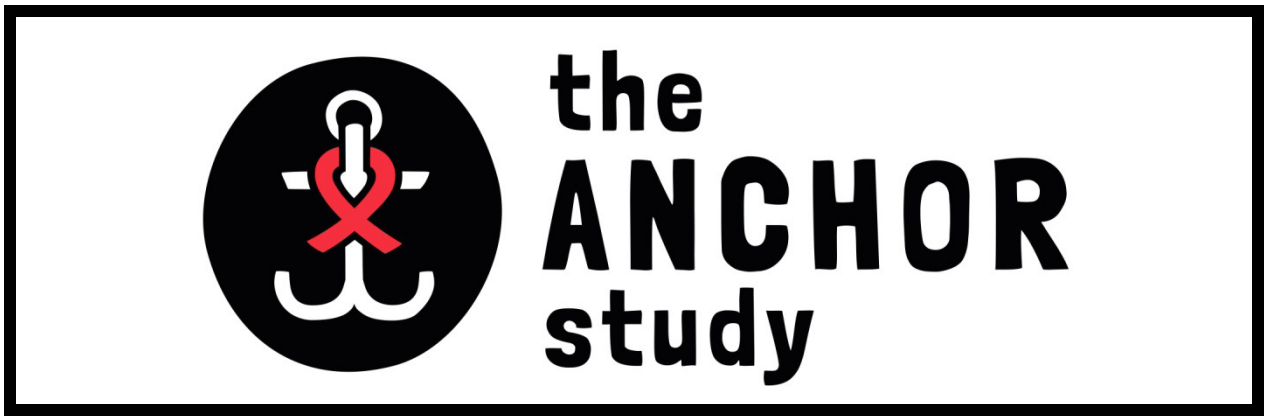


# Development of a Health-Related Symptom Index for Spanish-Speaking Persons Diagnosed with and either Treated or Monitored for Anal High-Grade Squamous Intraepithelial Lesions (HSIL)

## (AMC Protocol #A04)

### A Clinical Trial of the AIDS Malignancy Consortium

**To support evaluation of a Quality of Life (QOL) Instrument for the ANCHOR Study, Anal Cancer/HSIL Outcomes Research Study (AMC Protocol #A01)**

| | |
|---|---|
| **Sponsored by:** | National Cancer Institute<br>Office of HIV and AIDS Malignancy (OHAM) |
| **NCT Registration Number:** | NCT04276935 |
| **Protocol Chair:** | Thomas Atkinson, PhD |
| **Protocol Co-Chair:** | Yuelin Li, PhD |

*Version 5.0, November 8, 2022*
*NCI Version Date November 8, 2022*

## AMC PROTOCOL SIGNATURE PAGE

I, _____, Principal Investigator at site _____, agree to conduct and follow this protocol: **AMC Protocol #A04 – Development of a Health-Related Symptom Index for Spanish-Speaking Persons Diagnosed with and either Treated or Monitored for Anal High-Grade Squamous Intraepithelial Lesions (HSIL) (Version 5.0, 08NOV2022),** as written according to AMC, NCI, and OHRP guidelines. I understand that no deviations from the protocol eligibility criteria or waivers for protocol deviations will be permitted.

_____ _____

Signature Date (mm/dd/yyyy)

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**PROTOCOL ROSTER**

**AMC Protocol #A04**

**Development of a Health-Related Symptom Index for Spanish-Speaking Persons Diagnosed with and Either Treated or Monitored for Anal High-Grade Squamous Intraepithelial Lesions (HSIL)**


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**AMC Protocol #A04**

**Development of a Health-Related Symptom Index for Spanish-Speaking Persons Diagnosed with and Either Treated or Monitored for Anal High-Grade Squamous Intraepithelial Lesions (HSIL)**


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## SITES PARTICIPATING IN THE STUDY

Participation in this study is limited to the following AMC centers.

**Site performing participant survey methods:**

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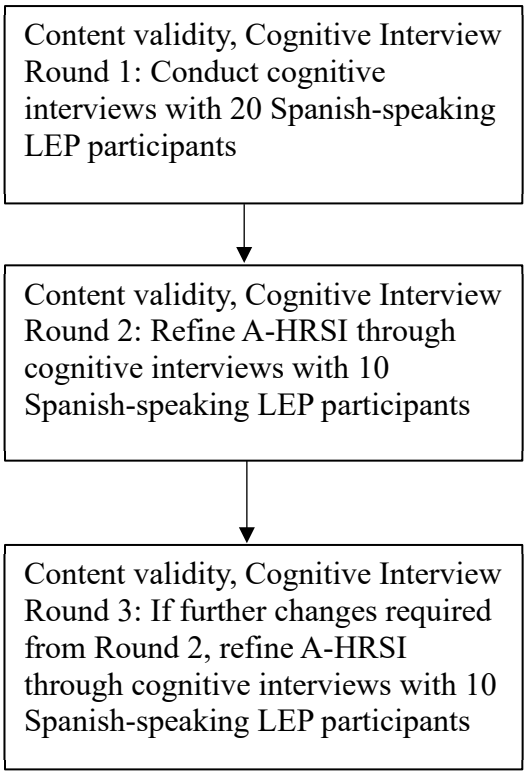
**ANCHOR trial sites for participant referrals:**

All interested sites that are participating in the AMC-A01 trial may participate if this protocol is determined to be exempt by the local IRB.

## PROTOCOL SYNOPSIS

| | |
|---|---|
| **Title:** | Development of a Health-Related Symptom Index for Spanish-Speaking Persons Diagnosed with and either Treated or Monitored for Anal High-Grade Squamous Intraepithelial Lesions (HSIL) |
| **Phase of Study:** | Observational |
| **Participating Institutions:** | This protocol will be conducted at Memorial Sloan Kettering Cancer Center (MSKCC) and will be open for participant referrals to MSK from participating ANCHOR sites. |
| **Accrual Target:** | Up to 40 participants |
| **Population:** | Participants who are Spanish-speaking with limited English proficiency (LEP), and who have been diagnosed with HSIL within the prior nine months will be recruited for all phases of ANCHOR HSIL HRQoL Index (HQI) development. |
| **Regimen:** | Procedures in this trial will be similar to the AMC-A02 protocol to validate the HQI instrument (anal Health-Related Symptom Index, or aHRSI) in the Spanish language, repeating phases 4-6 (cognitive interviews) with fluent Spanish speakers. This study will employ a translation of the current instrument being studied in English-speaking participants.<br>• Cognitive Interviews in Spanish (Round 1): We plan to consent 20 Spanish speaking participants in order to complete 20 cognitive interviews for feedback on the initial Spanish-language aHRSI draft.<br>• Cognitive Interviews in Spanish (Round 2): We will recruit up to 10 participants for this round with revised items tested in a second round of cognitive interviews with a smaller new cohort of HIV+ eligible participants.<br>• Cognitive Interviews in Spanish (Round 3): We will recruit up to 10 participants for this round, if further refinements to the Spanish-language aHRSI are indicated from the second round. |
| **Duration:** | One interview session (approximately 45-60 minutes) |
| **Primary Objective:** | To develop a Spanish-language version of the ANCHOR HSIL HRQoL Index (HQI) using state-of-the-art measure development methodology that captures the most important HRQoL symptoms and concerns of those persons diagnosed with anal HSIL and either treated or untreated for anal HSIL. |

## PROTOCOL SCHEMA



# 1.0 OBJECTIVES

## 1.1 Primary Objective

To develop a Spanish-language version of the ANCHOR HSIL HRQoL Index (HQI) using state-of-the-art measure development methodology that captures the most important HRQoL symptoms and concerns of those persons diagnosed with anal HSIL and either treated or untreated for anal HSIL.

Upon completion, the anal HSIL Symptom Index will be validated within the Anal Cancer/HSIL Outcomes Research Study (ANCHOR), a large randomized controlled trial. The ANCHOR protocol will be amended through the AMC and CTEP at that time.

## 2.0 BACKGROUND

### 2.1 Study Disease

Anal cancer is a growing problem in the United States. In the U.S. general population, the incidence of anal cancer from 2006-2010, was 1.5/100,000 among men and 1.9/100,000 among women. Human papillomavirus (HPV) infection is causally associated with the development of anal squamous-cell carcinoma. Anal HSILs are also associated with persistent HPV infection, and HPV DNA has been identified in 35 to 61% of squamous neoplasms of the anus, whereas nonmalignant anal epithelia are uninfected. More than 100 different types of HPV have been detected, of which about 30 types cause infection of genital mucosal sites. These are generally characterized as "high-risk" types (primarily HPV 16 and 18, but also 31, 33, 35, 39, 45, 51, and 52), which are associated with low-grade squamous intraepithelial lesions (LSILs), HSILs, and invasive cancer.

Compared with the general population, the standardized incidence ratio (SIR) of anal cancer has increased more than 100-fold among some risk groups of HIV-infected persons who are successfully treated with combination antiretroviral therapy (cART). Among men in the general population, the incidence is highest among Black men, at 1.9/100,000.[1] The American Cancer Society projected that there would be 7,090 cases and 880 deaths from anal cancer in 2013. The most recent data with actual number of cases were available from 2009. There were 2,210 cases of cancer of the anus, anal canal, and anorectum among males and 3,624 cases among females. There were 302 deaths among males and 516 among females from these cancers. The incidence of anal cancer is largely concentrated among several groups well-known to be at increased risk: men who have sex with men (MSM)[2]; HIV-infected men and women; men and women immunosuppressed for reasons other than HIV infection, including solid organ transplant[3,4]; women with a history of HPV-related cancer or high-grade squamous intraepithelial lesions (HSIL) elsewhere in the anogenital tract; and those with a history of genital warts. Of all the groups listed above the highest incidence of anal cancer is among HIV-infected men and women, particularly MSM[5,6]. Overall it is estimated that the proportion of individuals with anal cancer who are also infected with HIV increased from 1980-1984 to 2001-2005, rising from 1.1% to 28.4% among males, and from 0% to 1.2% among females. From 1980-2005, the HIV epidemic had little impact on the trends in anal cancer among females, among whom the incidence has been increasing annually by 3.3%.

However, the HIV epidemic has had a strong impact on the trends in anal cancer incidence among males, with an annual increase of 1.7% among men without HIV infection and 3.4% among men with HIV infection. The risk of anal cancer was elevated 52-fold in HIV-infected men who have sex with men (MSM), 32-fold in HIV-infected men, and 24-fold in HIV-infected women compared with the general population.

Several studies show an increase in the incidence of anal cancer since cART became available. While it is possible that better control of HIV infection with earlier initiation of cART may moderate the increased risk of anal cancer, the long-term effect of cART on anal cancer risk has not yet been studied. Moreover, among HIV-infected individuals, the great majority of people currently living with HIV were begun on cART later in the course of their HIV infection than is currently recommended. A recent meta-analysis estimated that 1 in 377 HIV-infected MSM with anal HSIL progress every year to anal cancer since

the introduction of cART[7], and since current cART has extended the life spans of HIV-infected individuals, this may result in a 10% lifetime risk of anal cancer or higher among HIV-infected MSM if nothing is done[8].

Taken together, these data highlight two important points: HIV-infected men and women are disproportionately affected by anal cancer, and the impact of HIV infection on anal cancer will likely continue to increase. Second, most of the cases of anal cancer in terms of absolute numbers occur among HIV-uninfected men and women, and thus the results of the ANCHOR study (Anal Cancer/HSIL Outcomes Research Study; AMC #A01; Joel Palefsky, M.D., ANCHOR PI, University of California, San Francisco), will impact on both HIV-infected and HIV-uninfected populations. In the absence of active intervention, the number of cases of anal cancer will likely continue to grow in the general population in the U.S. with varying degrees of contribution by the at-risk groups described above. Data on the global incidence of anal cancer are not as reliable but it is certain that there are many thousands more cases and deaths from anal cancer each year worldwide. Combined with the possibility that anal cancer is preventable, the incidence of anal cancer is unacceptably high and calls for urgent intervention.

## 2.2 Study Treatments

There are two approaches that may be used to prevent anal cancer. Primary prevention, in the form of vaccination against HPV infection may be useful to reduce infection with HPV, the underlying causative agent of anal cancer. Although there is great potential for HPV vaccination to reduce anal cancer in the long term, there are several limitations to this approach. Secondary prevention, which consists of screening for, and treating HSIL prior to progression to cancer, is the approach needed for the many individuals who have already been exposed to HPV and who have developed HPV-associated precancerous lesions. Like cervical cancer, most cases of anal cancer are caused by HPV 16 and HPV 18, and current cervical cancer prevention programs rely on both approaches, and in the long-term, it is likely that both will be needed for anal cancer prevention. The combination of low HPV vaccine uptake among vaccine-eligible men and women means that the full potential of the vaccine to reduce cancer incidence will likely not be realized unless rates of vaccine uptake improve. Combined with the fact that most HIV-infected men and women are too old for vaccination or were exposed to HPV 16 and 18 before vaccination became available, millions of men and women remain susceptible to HPV 16- and HPV 18-related HSIL and cancer. For these individuals, secondary prevention in the form of identifying and treating HSIL may be the only option to reduce the risk of anal cancer. Determination of the efficacy of HSIL treatment to prevent anal cancer is therefore a current and public health concern for the foreseeable future for this target population.

Treatment of HSIL. Treatment of anal HSIL in HIV-infected men and women is more challenging than in HIV-uninfected individuals. This is because HSIL tends to be larger in size and number in HIV-infected individuals. They may also recur more often at the site of prior treatment, and incident lesions may develop more often at sites that were not previously shown to have HSIL (metachronous lesions). Below are described the treatments for HSIL.

Ablative treatments. These treatments include Infrared coagulation (IRC), an office-based procedure using a therapeutic device that delivers short pulses of a narrow beam of visible

and infrared light through a small contact tip applicator applied directly to the target tissue, transmitted down the rigid quartz glass of the light guide. The tungsten-halogen lamp (150 watts of power) is the light source. This light causes thermal coagulation, which results in tissue necrosis. The depth of coagulation is determined by the total amount of energy delivered, and depth of tissue destruction is directly proportional to the duration of infrared impulses. The device is cleared by the Food and Drug Administration for use in the treatment of hemorrhoids, tattoo removal, chronic rhinitis, and anal condyloma. The procedure typically takes about 30 minutes to perform. It is generally well tolerated, and it is not uncommon for participants to go to work after the procedure. Overall the procedure is safe and can be performed by a wide variety of non-surgeon medical professionals. It requires only local anesthetic injected directly into or around the lesions to be treated. There may be occasional mild intra- and post-procedural pain, and bleeding for up to 2 weeks. There may also be mild textural changes of anal canal mucosa for several weeks post-procedure. The sequence of events is similar to that seen with cryosurgery: hemorrhagic blistering and necrosis of the treatment site followed by a shallow erosion and ulcer, and then healing over several weeks. There is a small risk of infection from the procedure. The risk of serious bleeding prompting emergency room evaluation is <1%.

Hyfrecation/electrocautery is an ablative technique with a long history of use in the operating room and the office for the treatment of HPV-associated anal lesions. A recent publication showed no statistically significant differences between electrocautery and IRC in their efficacy and safety profile. In the ANCHOR study, clinicians may use electrocautery interchangeably with IRC. The choice of therapy typically depends on the prior training of the clinician and the technique with which they have the most experience. Non-surgeons in the U.S. who treat anal HSIL were primarily trained by Dr. Palefsky and his group to use IRC, but those with a surgical background may prefer electrocautery. The main advantages of electrocautery are that it is faster than IRC to perform and the electrocautery probe tip can be more precisely applied to the lesion than the IRC probe tip, which is larger in diameter. The main disadvantage of electrocautery is that it generates a smoke plume, requiring a smoke evacuator and mask protection from smoke for providers and patients in the room.

Other ablative treatments include use of surgical lasers. These modalities are less commonly used for anal HSIL, but patients treated with these techniques will be eligible for the HRQoL study.

Treatment under anesthesia (TUA) is a procedure performed by surgeons on patients who are given spinal or general anesthesia. It is typically performed in an operating room although some procedures may be performed in an office setting on patients with conscious sedation. Combined with post-procedural IRC, it has been shown to be effective in treatment of HSIL for patients with disease too widespread to treat with targeted ablation therapy[9]. TUA is usually required for only a small percentage of patients being treated for anal HSIL. These include 1) disease that is so extensive that it cannot be treated by any of the other methods described in this section, or 2) if a lesion is so large that it cannot be sufficiently biopsied in the office to establish or exclude a diagnosis of cancer to the satisfaction of the clinician. The disadvantage of TUA is that it is expensive compared with the other methods. In addition, TUA is only done when more extensive excision is required and patients typically experience more post-procedure side effects, including pain,

bleeding, and infection after TUA when compared with less aggressive treatment modalities.

Topical agents. Topical 5% fluorouracil cream (5-FU) is typically used when disease is too extensive for IRC or electrocautery. It is given with the intent to clear as much of the lesion as possible, and while it is unusual for a large lesion to clear completely, it may be particularly useful to "debulk" a lesion to the point where it can them be treated with a targeted ablative approach such as IRC or electrocautery. Among 20 patients with extensive HSIL who were treated with topical 5-FU at UCSF by the PI's team, complete response was seen in only 3 and no response was seen in one, but 16 had a significant decrease in volume of disease to 25-50% that allowed for in-office IRC. At UCSF, the protocol for use of topical 5-FU is for the patient to apply intra-anal or perianal 5-FU twice daily for 5 days, followed by a 9-day rest period. This cycle can be repeated eight times.

Like 5-FU, 5% imiquimod cream is a topical agent that has typically been used when the extent of disease has been too large to allow for use of a targeted ablative modality such as IRC or electrocautery. Imiquimod has been used for treatment of external genital condyloma since 1997. It is a synthetic compound that exhibits antiviral activity by up-regulating the immune response, at least in part through toll-like receptors. It may lead to a Th1 cytokine response that activates HPV-specific cell-mediated immunity and clearance of lesions. Imiquimod has been used for treatment of HPV-associated mucosal disease including vulvar, penile, and anal SIL. The advantage of imiquimod is that, like topical 5-FU cream it can be used to treat extensive disease that is too large for targeted ablation. It has a long safety record for treatment of condyloma, including in the setting of HIV infection. The disadvantages of imiquimod are side effects may be severe, particularly when patients are experiencing a robust clinical response. These may be local irritation or pain, or may be systemic flu-like symptoms. Another disadvantage is that there are relatively few randomized study data on the efficacy of imiquimod in treatment of perianal or anal disease. Imiquimod has not been studied formally in the U.S. The AMC HPV Working Group was recently approved by CTEP to perform a randomized trial of imiquimod vs. 5-FU vs. observation for extensive HSIL in HIV-infected men and women. Despite limited data, imiquimod is on the list of treatment modalities available to ANCHOR study clinicians but that may change pending the outcome of the AMC study described above or other study data as they become available. The treatments described above are used routinely by clinicians involved in treating HSIL. Except for TUA, which is expected to be necessary for only a very small percentage of participants with HSIL, each is readily available for use in the office setting by a wide variety of medical professionals, including physicians, nurse practitioners, and physician assistants.

Active monitoring or observation is the control arm of the ANCHOR study, and this approach is used clinically in a small percentage of cases. Given the diversity of treatments for anal HSIL, it is important that the participant sample recruited for the development of a symptom index measure include representatives of all the treatment modalities, including those not treated but actively monitored. It is expected that some participants will have been treated with multiple modalities; thus, these participants will be included in the HRQoL study as well.

## 2.3 Study Design and Rationale

The ANCHOR study presents a unique opportunity for the measurement of health-related quality of life (HRQoL) among those diagnosed with HSIL, as no measure currently exists that captures the symptoms and related experiences of living with or being treated for HSIL. HRQoL is a "multi-domain concept that represents the participant's general perception of the effect of illness and treatment on physical, psychological, and social aspects of life."[10] Devising a symptom index, as opposed to developing a full HRQoL measure, is a pragmatic approach developed and recommended by HRQoL expert and study consultant Dr. David Cella to address the short time frame for measure development and implementation in the ANCHOR trial, and as a solid first step in assessing symptoms and HRQoL in this context. An index is a compilation of symptoms and concerns and typically does not have the more complex subscale structure of existing HRQoL measures[11]. An index has the benefits of being briefer than existing HRQoL measures (e.g., < 20 items vs. 40+ items) more focal, quicker to implement, and is supported by methodologies and findings from multiple studies of Dr. Cella's research team[12]. The AMC-A02 study developed a HRQoL Symptom Index for HSIL and its treatment in the HIV-infected population.[18] This trial seeks to develop a Spanish-language version of the HRQoL Symptom Index, the anal Health-Related Symptom Index (aHRSI), among Spanish-speaking persons with limited English proficiency (LEP).

There is a paucity of data on symptoms and concerns of persons diagnosed and treated for anal HSIL. In one prospective study from the ANCHOR PI's research team[13], a small sample (n=37; 29 of whom were HIV-positive; mean age of 45.8 years) of persons diagnosed with HSIL were treated with surgical excision and followed every 3-6 months for a mean of 32 months. The primary aim of the study was to demonstrate the safety and efficacy of high-resolution anoscopy and surgical treatment for diagnosed HSIL. A specific set of symptoms and concerns were assessed: Uncontrolled pain, persistent bleeding, perianal abscess formation, late development of anal stenosis, and alteration in anal continence or sexual function. Approximately half of the patients (16/29) reported uncontrolled pain after the procedure that lasted for a mean of 2.9 weeks (range 1 to 120 days). Most of the pain experienced was associated with bowel movements. No patients required reoperation for abscess or bleeding, or experienced clinically significant stenosis or incontinence to formed stool. Twenty-four (83%) of 29 patients reported receptive anal intercourse before surgery, and 21 of these 24 resumed receptive anal intercourse after an average duration of 5.7 months. Those who did not resume receptive anal intercourse did so for reasons not clearly attributable to surgery. These data, although emanating from one small study using only one of several treatment modalities, suggest that HRQoL concerns are substantial after treatment for anal HSIL. It is important to assess physical symptoms and concerns in those living with or treated for anal HSIL, as these may be important considerations in treatment decision-making for patients and their physicians, especially in the context of an ANCHOR finding of equivalent effectiveness of active treatment vs. active monitoring at the trial's end.

A second study examined psychological symptoms associated with anal cancer screening (high resolution anoscopy) in 104 HIV-positive MSM in primary care and HIV clinics in Canada[14]. Data were collected with multiple standardized measures of psychological distress at four time points during the study: time 1 (within a week before the initial visit),

time 2 (within a week after the initial visit), time 3 (within a week after receiving results), and time 4 (within a week before the follow-up visit (usually at 6 months). Only a small proportion of the sample (11%) was found to have HSIL, and these were treated with either IFC or imiquimod. The study found that being screened for precursors of anal cancer was not associated with high levels of adverse psychological consequences in most patients. The time of greatest negative impact was immediately after having the screening tests. The proportion of patients experiencing higher levels of negative impact tended to diminish over the four time points, and the positive effects of being screened seemed to increase as time went on. Younger patients and those who had more HIV symptoms and higher psychological distress scores at baseline were more likely to experience higher levels of negative psychological impact from screening. There were too few patients with HSIL to perform meaningful adjusted analyses, but there was a tendency for such patients to experience higher levels of negative impact just before returning for follow-up, but not after receiving their results. The increased stress may be a result of the treatment for HSIL, which patients would have received between times 3 and 4, although these findings should be interpreted with caution given the very small numbers of patients with HSIL. Thus, these findings indicate that, in addition to assessing physical symptoms, a HRQoL instrument specific to anal cancer screening and HSIL treatment must also assess psychological symptoms.

In consultation with the AMC's expert clinicians who treat anal HSIL, the research team has learned that not only modality of treatment can impact peri- and post-treatment symptoms, but volume of disease can as well. A larger volume of disease may mean a more intensive treatment, leading to prolonged or more severe physical and behavioral/psychological symptoms. Thus, this study will incorporate low vs. high volume of disease, defined in the ANCHOR Study protocol as anal HSIL that occupies less than 50% or 50% or more of the anal circumference, as a parameter of recruitment of the participants for this study in order to assure that both levels of disease volume are represented.

AMC-A02 aimed to develop a symptoms index (a more focal type of health-related quality of life (HRQoL) measure) for persons diagnosed with, and either treated or monitored for, anal high grade squamous intraepithelial lesions (HSIL). Once developed, the measure will be implemented within the NCI-funded, AIDS Malignancy Consortium's ANCHOR trial (AMC #A01; Anal Cancer/HSIL Outcomes Research Study; Joel Palefsky, M.D., PI, UCSF) to confirm validity and reliability.[18] In the ANCHOR trial, persons infected with human immunodeficiency (HIV) are the sample population, as HIV-positive persons are at significantly elevated risk for HSIL and anal cancer. The primary aim of the ANCHOR trial is to determine the effectiveness of treating anal HSIL to reduce the incidence of anal cancer in HIV-infected men and women. The ANCHOR trial opened to accrual in September 2014, and the NCI CTEP review has recommended the development of a HRQoL measure appropriate to the ANCHOR trial's target population and treatment or active monitoring study arms. No such measure currently exists; hence, it is important to devise such a measure, especially if the ANCHOR trial supports the effectiveness of HSIL screening and treatment in reducing the risk of anal cancer. Given the short time frame of funding made available to conduct the measurement development, imminent ANCHOR recruitment, and minimal risk from study participation, the MSKCC research team and recruitment sites are dedicated to assuring the privacy of the non-MSKCC participants

participating in this study.

To this end, we conducted a multi-phase, methodologically rigorous, qualitative data collection and analysis scheme involving: 1) Phase 1, Expert Consultation: Identification and listing of important symptoms and concerns of HSIL participants from the perspective of expert clinicians within the AIDS Malignancy Consortium (AMC); consultation with Dr. David Cella, author of the FACIT HRQoL measures, regarding study methodology and use of existing items from the FACIT item bank that have been validated so as to assess domains identified by expert clinicians; 2) Phase 2, Concept Elicitation: Independent elicitation of important symptoms and concerns from eligible HIV-positive participants referred from five ANCHOR/AMC sites (Weill Cornell Medical College/NYPH; Montefiore Medical Center; Laser Surgery Care Center; UCSF and the Anal Dysplasia Clinic Midwest), as well as their responses to symptoms and concerns identified by expert clinicians in the initial phase; 3) Phase 3, Initial Measure drafted of an HRQoL measure based upon the expert and participant feedback from Phases 1 and 2; 4) Phase 4: Cognitive interview round 1 with a second cohort of eligible HIV-positive participants for feedback on the initial HRQoL Draft from Phase 3; 5) Phase 5: Cognitive interviewing round 2 , with revised items tested in a second round of cognitive interviews with a smaller new cohort of HIV-positive eligible participants; and 6) Phase 6, Cognitive interviewing round 3, a final round of cognitive interviews with a small new cohort of HIV-positive eligible participants if further refinements are indicated from the second round.[18]

This study adds a seventh phase to the development paradigm conducted with protocol AMC-A02, which will use the translated aHRSI in Spanish to complete cognitive interviews of Spanish-speaking participants. We will be conducting cognitive interviews (see Appendices VI and VII) of the finalized measure in Spanish (see Appendices XI and XII) to establish the content validity of the measure in Spanish. In addition to the cognitive interviews, we will collect a brief demographic form, and collect information on the participants preferred language and language proficiency (see Appendices IX, X, XIII, and XIV) for each participant. We will enroll up to 40 eligible HIV-positive participants from participating ANCHOR sites using the same eligibility criteria as AMC-A02 phase 2 (except the age limit is lowered to 18 and the added criteria that Spanish be their first language as per self-report) over three rounds of cognitive interviewing, as was done for the English language version in AMC-A02 phases 4-6.[18]

- Cognitive Interviews in Spanish (Round 1): The process for conducting the cognitive interviews will be the same as for the English ones outlined above in Phase 4. We will plan to consent 20 Spanish speaking participants in order to complete 20 cognitive interviews.
- Cognitive Interviews in Spanish (Round 2): We will complete Phase 5 in Spanish in the exact same method as we did for the English version if it is necessary. If necessary, we will recruit up to 10 participants for this Phase 5 round.
- Cognitive Interviews in Spanish (Round 3): We will complete Phase 6 in Spanish in the exact same method as we did for the English version if it is necessary. If necessary, we will recruit up to 10 participants for this Phase 5 round.

## 3.0 PARTICIPANT SELECTION

Participants who have been diagnosed with HSIL within the prior nine months will be recruited for all phases of this protocol. The target population is volunteers who meet all the inclusion/exclusion criteria, and who are presumed eligible for the ANCHOR study. Recruiting sites will be responsible for referring participants into the HRQoL Index study who meet the eligibility criteria listed below.

### 3.1 Eligibility Criteria

3.1.1 HIV-1 infection

3.1.2 Age 18 years or older. This age restriction is intended to enrich the study population at risk for cancer since anal cancer occurs only rarely under this age even among HIV-infected individuals. Less than 1% of anal cancers occur under the age of 35 years[15].

3.1.3 Biopsy-proven anal HSIL within the prior nine months

3.1.4 Participant must have received anal HSIL treatment in the last nine months. If the participant's treatment plan is "observation," the participant must have been diagnosed with anal HSIL in the last nine months.

3.1.5 Life expectancy of greater than 5 years

3.1.6 Fluent in Spanish with limited English proficiency, per self-report

### 3.2 Exclusion Criteria

Participants who do not fulfill the criteria as listed in Section 3.1 above, are ineligible. Additionally, the presence of any of the following conditions will exclude a participant from study enrollment:

3.2.1 History of anal cancer

3.2.2 Inability to understand a written consent form

### 3.3 Number of Participants to be Enrolled

3.3.1 Proposed sample size

This study will enroll a minimum of 20 participants and a maximum of 40 participants.

3.3.2 Accrual rate

Approximately 5 participants per month.

### 3.4 Participant Referral and Enrollment Procedures

This study will be recruiting from any sites participating in AMC-A01 as long as this protocol is determined to be exempt by the local IRB. Each recruitment site PI has agreed to participate and will identify and refer eligible patients. Upon MSKCC IRB approval, the exempt protocol will be provided to the PI at each recruitment site for review by their IRB. Once each site's IRB approval is obtained, each site will be provided with instructions on the referral process and a list of site-specific unique identification numbers that will be used for each patient referral. Referring sites will not collect any data; they will only be

responsible for assuring eligibility of all patient referrals. After confirming a patient's eligibility, the site physician or designee will provide an Information Sheet about the study containing the MSK RSA contact information, financial and transportation compensation information, and the unique identification number. The Information Sheet will have a gray box on the top stating "This box for Clinician Use Only. Clinician, please circle appropriate letter." The appropriately circled letters will create the unique identification number. It will be up to the patient to initiate a call to the MSK RSA, although one or more sites may provide telephone access within their clinics for referred patients to call the MSKCC contact. The unique identification number will have encoded information regarding from which site the patient has been referred, which of four treatment modalities the patient used, and the volume of disease. The encoding will not be interpretable by anyone except the referring site and the MSKCC study staff. For example, Laser Surgery Center will be given Information Sheets with referral numbers 100-199, Einstein Montefiore will be given Information Sheets with referral numbers 200-299 and 400-499 (Dr. Levine's clinic), and Weill Cornell will be given Information Sheets with referral numbers 300-399. Treatment modality will then be indicated by circling the first letter of the correct treatment modality. For example, a participant who is being observed without treatment will be represented with a circled "O," Ablative with a circled "A," Topical with a circled "T," and Surgery with a circled "S." If the patient has undergone multiple treatment modalities, the referral staff will select the most recently received treatment. Next, disease volume will be indicated by circling either L or H. L will correspond with HSIL lesion size covering Less than or equal to 50% of the anal canal/perianal region and H will correspond with HSIL lesion size covering Higher than 50% of the anal canal/perianal region. An example code could then be 100-AL; this indicates the patient was referred from Laser Surgery Center, has received ablative treatment, and has HSIL lesion covering less than 50% of the anal canal/perianal region. It is important that the referral site indicate via the treatment code how each patient was treated, and the volume of disease, because patients may not accurately report treatment modality. The sampling strategy must be monitored by the MSKCC study staff in order to assure proper patient sampling.

### 3.4.1 Referral process

MSKCC will provide the participating sites with instructions on how to refer study participants. The referral process will include a list of site specific unique identification numbers that will be used for each participant referral. Referring sites will not collect any data and they will only be responsible for assuring eligibility of all participant referrals.

After confirming a participant's eligibility, the site physician or designee will provide an Information Sheet (Appendices I and II) about the study containing the MSK RSA contact information with the unique identification number on the Sheet. It will be up to the participant to initiate a call to the MSK RSA, although one or more sites may provide telephone access within their clinics for referred participants to call the MSKCC contact.

When a referred patient calls the MSK RSA and expresses interest in participating in the study and all questions are answered, the patient will be asked to provide the unique study ID and her/his name and telephone number(s) for the purpose of scheduling matters only. The patient will be offered an appointment date/time for

the interview to be held at MSK or completed over the phone. Once the scheduling is done but before the date of the interview, the RSA will call the referring site for that patient to confirm patient eligibility in cases where the referred patient is not calling directly from the referring site clinic. This is to assure verbally that the referred patient meets the eligibility requirements and is the same person referred by that site.

The MSKCC screening log for each participant will be destroyed once the participant has completed the interview, declined to participate further, or after three follow-up telephone calls when a missed or rescheduled interview appointment occurs for those participants agreeing to participate.

3.4.2 Participant visit procedures

When the patient is seen or contacted by phone for the interview, the RSA will review the Information Sheet [see Appendices I and II] with the patient, solicit questions, and ask for verbal agreement to participate in the interview. We will not collect documented informed consent in an effort to maintain the participant's anonymity. If the patient does not wish to participate, the session will be ended, and no further contact will be initiated by the MSK staff. If the patient agrees to participate, then the RSA will ask for gender identity, age, education, and race/ethnicity in order to be able to describe the sample of patients for this study. No name or other PHI will be associated with these sociodemographic data, only the study-assigned ID#. A digital audio recording of the session will commence once the interview begins for the purpose of generating a summary report of the interview by the RSA. These recordings will be destroyed within 48 business hours of the interview and will only be examined by the RSA or other staff as needed to clarify interview content in reference to the notes taken by the RSA during the interview. No transcripts will be generated from the audio-recordings. The RSA notes and summary will be identified only with the unique identification number of the referral. No names, telephone numbers, or other identifying information will be associated with any study data.

All patients will be offered $50 in cash or money order.

## 4.0 RESEARCH PLAN

The HSIL symptom index development and validation process for AMC-A02 proceeded through six phases.[18] In phase seven we have translated the aHRSI to Spanish and will complete cognitive interviews in Spanish. We will be conducting cognitive interviews (see Appendices VI and VII) of the finalized measure in Spanish (see Appendices XI and XII) to establish the content validity of the measure in Spanish. In addition to the cognitive interviews, we will collect a brief demographic form and collect information on the participants preferred language and language proficiency (see Appendices IX, X, XIII, and XIV) for each participant. We will enroll up to 40 eligible HIV-positive participants from enrolling ANCHOR sites.

## 5.0 STATISTICAL CONSIDERATIONS

As a research project involving survey measures and cognitive interviewing, no formal statistical analysis plan is required. Respondents' interviews will be abstracted and coded for analysis by an expert panel.

## 6.0 ROLE OF DATA MANAGEMENT

### 6.1 CRF Instructions

The required study forms, surveys, and instructions will be developed and maintained by MSKCC.

### 6.2 Data Quality

It is the responsibility of MSKCC to assure the quality of data for the study. This role extends from protocol development to generation of the final study database.

### 6.3 Data Monitoring

As an exempt survey research project, this trial will not collect identifiable data from trial participants. This study will be monitored in compliance with MSKCC policies. MSKCC is responsible for compiling and submitting data for all participants and providing the data to the research team for review.

## 7.0 ETHICAL AND REGULATORY CONSIDERATIONS

This research project meets the criteria for exemption from the requirements for Institutional Review Board (IRB) approval and informed consent described in the Department of Health and Human Services (DHHS) regulations for the Protection of Human Subjects regulations (45 CFR Part 46). Each participating institution will be required to provide written confirmation from the IRB of record for this exemption before initiating participant enrollment. The sponsor's designee (ANCHOR DMC) will maintain this record. The IRB must also approve any significant changes to the protocol and documentation of this approval must be sent to the ANCHOR DMC.

Records of all study review and approval documents must be kept on file by the Investigator and are subject to inspection during or after completion of the study. The IRB should receive notification of completion of the study and final report within 3 months of study completion and termination. The Investigator will maintain an accurate and complete record of all submissions made to the IRB, including a list of all reports and documents submitted, as applicable for exempt research projects.

### 7.1 Justification for Exemption

This study involves prospective collection of human data that will be stored at MSKCC. The data collected include audio-recorded feedback by participants on the HSIL measure developed in AMC-A02 and translated into Spanish. The audio recordings will be stored on a secure MSKCC server for a maximum of 48 business hours. Only individuals on our study team will have access to these audio recordings. Audio recordings will not be transcribed; rather, they will be referred to when drafting the summary report of each participant to ensure accuracy of the report. Names will not be used (only a study ID number). The recording will be deleted from the server within 48 business hours of its creation. Data collected and created on paper (i.e., semi-structured interviews and summary reports) will also be saved on the secure MSKCC server and only identified through their ID number.

The specific health data that will be collected for this study includes treatment modalities used and binary data on the extent of anal HSIL. Because it is important to sample participant experiences across the four treatment modalities, including active monitoring, in a way proportional to the treatment practices of clinician experts informing the study, we will record the treatment modality used for each participant's anal HSIL.

PHI collected will be limited to name, telephone numbers, and audio recordings (voice print). Once participants have been referred to the study by their doctor and contact the study staff, we will ask for their name and phone number solely for the purpose of scheduling the interview and confirming eligibility with the referring site. The participant will be offered an appointment date/time for the interview to be held at MSK. Once the scheduling is done but before the date of the interview, the study staff will call the referring site for that participant to confirm eligibility. This is to assure verbally that the referred participant meets the eligibility requirements and was referred by that site. As sites will vary in their facilitation of referrals, no call will be made when participants are calling directly from the referring clinic, per prior arrangement with the study staff. The contact information (name and phone number) for each participant will be destroyed once the participant has completed the interview, declined to participate further, or after three

follow-up telephone calls when a missed or rescheduled interview appointment occurs for those participants agreeing to participate.

This PHI will be stored in the clinic's records and will only be accessible to the following staff at MSKCC until destruction: Thomas Atkinson, PhD; Yuelin Li, PhD, Department of Psychiatry and Behavioral Sciences, Behavioral Sciences Service.

Participant PHI (name, phone number) will only be retained until the interview has been completed or the participant has been lost to follow-up due to non- response to rescheduling the interview, which is 3 telephone calls. This information will be stored on the secure MSKCC server. Once the interview is completed or three telephone calls have been attempted, the PHI will be destroyed.

This project could not reasonably be conducted without a waiver of informed consent. Because HIV-positive persons are a vulnerable population, we have taken great care in protecting their privacy while assuring sound measure development methodology. As part of this protection, we will NOT collect documented informed consent as this could pose a threat to the participants' anonymity, which we are trying to maintain. Each potential participant will be referred to this study by their physician or physician's clinical staff. It will be up to each potential participant to contact MSK about participation. If they are interested, MSK study staff will ask for their name and phone number and obtain verbal agreement to participate. We will then contact the referring site to confirm eligibility. Once their participation in the study is complete we will destroy all contact information and audio recordings after which each participant in study will be completely anonymous. If we collected documented informed consent, we could not assure each participant of this level of anonymity.

This research could not practicably be conducted without a waiver of HIPAA authorization. Because HIV-positive persons are a vulnerable population, we have taken great care in protecting their privacy while assuring sound measure development methodology. As part of this protection, we will NOT collect documented informed consent as this could pose a threat to participant's anonymity, which we are trying to maintain. Each potential participant will be referred to this study by their physician. It will be up to each potential participant to contact MSK about participation. If they are interested, MSK study staff will ask for their name and phone number and obtain verbal agreement to participate. We will then contact the referring site to confirm eligibility, unless other arrangements have been made in advance, such as calling the participant directly from the referring clinic. Once their participation in the study is complete, we will destroy all contact information and audio recordings, after which each participant in the study will be completely anonymous. If we collected documented informed consent, we could not assure each participant of this.

The research could not practicably be conducted without access to PHI because the PHI is needed to identify eligibility for the study. As part of the eligibility criteria for participation in the study, we need HIV-positive participants being treated for HSIL. We have designed a recruitment method based on referrals from site physicians who will be well trained in the eligibility criteria. This referral-based recruitment method is being used to protect the potential participants, as PHI is needed to determine eligibility. The PHI is also needed to answer the research question, by describing the study sample's gender, age, ethnicity, education, and HSIL treatment modality.

The qualitative data collected from study participants will be used to develop a preliminary HSIL symptom index measure that must be validated and will be done so in the ANCHOR Study; thus, there are no data to be shared until the end of the ANCHOR Study.

The procedures outlined above in this minimal risk study offer comprehensive protection of the privacy of participants. All resulting qualitative data (handwritten notes and summaries) will be completely de-identified, and all screening logs will be destroyed so that no PHI is linked to the data. Data collected in the study will only be used and reported in the aggregate for the purpose of describing the study sample and devising items that assess the symptoms and concerns related to HSIL diagnosis and treatment. Furthermore, none of the information collected through interviews presents any risk to the participants. The final measure resulting from the above process will then be implemented into the ANCHOR trial for the purpose of testing validity and reliability.

## 7.2 Changes to the Protocol

Any change or addition to this protocol requires a written protocol amendment that must be approved by the Protocol Chair before implementation. All protocol amendments require approval by the IRB of each participating institution. A copy of the written approval of the IRB must be obtained before implanting those changes.

## 7.3 Subject Confidentiality

Because HIV-positive persons are a vulnerable population, we have taken great care in protecting their privacy while assuring sound measure development methodology. For the referral process from the three participating NYC sites, we have sought and received their assurance that the research procedures described herein constitute exempt research at their respective institutions. This exempt protocol will be provided to the PI at each recruitment site for review by their IRB. Once site IRB approval is completed, each site will be provided with instructions on the referral process and a list of site-specific unique identification numbers that will be used for each participant referral. Referring sites will not collect any data; they will only be responsible for assuring eligibility of all participant referrals.

Furthermore, until study-specific records containing PHI and are destroyed by MSKCC, those records will be maintained in compliance with existing local standards for data security and confidentiality to prevent unauthorized access to confidential participant information. In accordance with the AMC's Certificate of Confidentiality, clinical information will not be released without the written permission of the subject, except as necessary for monitoring by the ANCHOR Study/AMC, the IRB, the NCI, the OHRP, or designee.

## 7.4 Study Discontinuation

The study may be discontinued at any time by the AMC, IRB, NCI, OHRP, or other government agencies as part of their duties to ensure that research subjects are protected.

## 7.5 Women and Minorities

This study is being conducted by the NCI-sponsored AIDS Malignancy Consortium (AMC). As part of their contractual obligations, each participating site within the AMC and the AMC as a whole is required to assure that the participation of women and minority

subjects reflects the percentage representation of these populations in their geographic region and, for the AMC, the United States as a whole. As such, it is expected that the representation of subjects on this trial will reflect the constitution of the respective populations.

**Table 1. Accrual Targets**

| Ethnic Category | Sex/Gender | | | | |
|---|---|---|---|---|---|
| | **Females** | | **Males** | | **Total** |
| Hispanic or Latino | 6 | + | 34 | = | 40 |
| Not Hispanic or Latino | 0 | + | 0 | = | 0 |
| Ethnic Category: Total of all subjects | 6 | + | 34 | = | 40 |
| Racial Category | | | | | |
| American Indian or Alaskan Native | 0 | + | 0 | = | 0 |
| Asian | 0 | + | 0 | = | 0 |
| Black or African American | 2 | + | 10 | = | 12 |
| Native Hawaiian or other Pacific Islander | 0 | + | 0 | = | 0 |
| White | 3 | + | 21 | = | 24 |
| More than one Race | 1 | | 3 | | 4 |
| Racial Category: Total of all subjects | 6 | + | 34 | = | 40 |
| | (A1 = A2) | | (B1 = B2) | | (C1 = C2) |

## 8.0 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by the AMC's Standard Operating Procedures for Publication Policy.

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| This box for clinician use only. Clinician, please circle appropriate letter. | | |
|---|---|---|
| **Referral Number** | **Treatment** | **Volume** |
| 99-xxxx | **O A T S** | **L H** |

## APPENDIX I: REFERRAL INFORMATION SHEET - ENGLISH

## Development of a Symptom Index for Spanish-Speaking Persons Diagnosed with, and either Treated or Monitored for Anal High-Grade Squamous Intraepithelial Lesions (HSIL)

***What is the purpose of this study?***

The purpose of this study is to develop a questionnaire that measures health-related symptoms and concerns for persons diagnosed with, and either treated or monitored for, anal high-grade squamous intraepithelial lesions (HSIL) that can be understood by Spanish speaking participants.

***Who can participate?***

We are looking for about 40 HIV-positive patients who have been treated or monitored for anal HSIL for whom Spanish is their first language. We will recruit participants from 14 approved ANCHOR referral sites across the United States. Because anal HSIL is treated by different methods, we are looking for participants receiving each treatment method.

***What do I have to do as a participant in this study?***

If you choose to be in the study, your participation will involve an individual, private interview either in person or over the phone that will take about 60-90 minutes. If the interview will be completed in person it will take place at the Memorial Sloan Kettering Cancer Center, Department of Psychiatry & Behavioral Sciences, at 641 Lexington Ave (at 54$^{th}$ Street). The interviews will be audio recorded to make sure all the information you provide is written into a summary report. The recording will be destroyed within 48 business hours of the interview. No one but the study staff will have access to these recordings for those 48 hours.

***How long will it take?***

Participants will be in the study for about 1.5 hours during one in person or phone visit only.

***What are the risks and benefits of participating in the study?***

You may be asked to answer questions about private matters that relate to your present state of health, which could cause you to feel a loss of privacy. You may decline to answer any of the questions presented during the interview session, and you may ask any questions about this study and the interview at any time. Please tell the study staff if you feel uncomfortable or upset during the interview process. They will make sure that the study doctor will follow up with you within 24 business hours.

Your responses may help researchers develop better questionnaires to understand the health-related experiences and symptoms due to having HSIL or being treated for HSIL. Knowing this might help people in the future make decisions about treating HSIL. For your time and effort, you will receive $50 and travel compensation once you complete the interview. If you complete the interview over the phone, we will need to ask for your mailing address. We will write the mailing address on the envelope to be mailed to you with a $50 money order and thank you letter enclosed. Your mailing address will not be recorded anywhere else.

***Is this confidential?***

Yes. Names and contact information will **NOT** be collected, stored or appear on any research data or reports.

***Further questions?***

Our research study staff would be happy to answer any additional questions. You can reach our study staff, at: (**646) 888-0123** to schedule an interview appointment. Tom Atkinson, PhD, Department of Psychiatry & Behavioral Sciences, can be reached at: (**646) 888-0089**. For a non-physician whom you may call for more information about the research participation process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: **(212) 639-8254**.

***Thank you for taking the time to learn more about our study!***

| This box for clinician use only. Clinician, please circle appropriate letter. | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Referral Number** | | **Treatment** | | | | **Volume** | |
| **99-xxxx** | **O** | **A** | **T** | **S** | | **L** | **H** |

## APPENDIX II: REFERRAL INFORMATION SHEET - SPANISH

### Desarrollo de un índice de síntomas para personas diagnosticadas con lesiones intraepiteliales escamosas anales de alto grado que han sido o tratadas o monitoreadas

***¿Cuál es el propósito de este estudio?***

El propósito de este estudio es desarrollar un cuestionario que pueda ser entendido por hispanohablantes, que mida los síntomas e inquietudes relacionados con la salud para las personas diagnosticadas con lesiones intraepiteliales escamosos de alto grado (en adelante HSIL según sus siglas en inglés), que han sido o tratadas o monitoreadas.

***¿Quién pude participar?***

Buscamos alrededor de 40 pacientes VIH+ que hayan sido tratados o monitoreados para HSIL anal y para quienes el español sea su primer idioma. Reclutaremos participantes de 14 centros de derivación aprobados por ANCHOR en los Estados Unidos. Debido a que el HSIL anal se trata por medio de métodos diferentes, buscamos participantes que estén recibiendo cada método de tratamiento.

***¿Qué debo hacer como participante en este estudio?***

Si desea ser parte del estudio, usted participará en una entrevista privada e individual por teléfono o en persona que durará aproximadamente 60-90 minutos. Si la entrevista ocurre en persona tomará lugar en Memorial Sloan Kettering Cancer Center, Departamento de Psiquiatría y Ciencias Conductuales, en 641 Lexington Ave (Calle 54). Las entrevistas serán grabadas para asegurarnos de que toda la información que nos bride pase a ser parte de un resumen escrito. Las grabaciones serán destruidas en un plazo de 48 horas hábiles de realizada la entrevista. Solamente el personal del estudio tendrá acceso a estas grabaciones durante esas 48 horas.

***¿Cuánto tomará?***

Los participantes estarán en el estudio por aproximadamente 1.5 horas más o menos durante una llamada telefónica o visita en persona únicamente.

***¿Cuáles son los riesgos y beneficios de participar en el estudio?***

Se le podría pedir que conteste preguntas referentes a asuntos privados que se relacionan con su estado de salud actual, lo cual podría hacerlo sentir que está perdiendo su privacidad. Usted podrá negarse a contestar cualquiera de las preguntas que le hagan durante la entrevista, y podrá hacer cualquier pregunta sobre este estudio y la entrevista en cualquier momento. Por favor comuníquele al personal del estudio si se siente incómodo o molesto durante la entrevista. Ellos se asegurarán de que el médico del estudio le haga un seguimiento en un plazo de 24 horas hábiles.

Sus respuestas podrían ayudar a los investigadores a desarrollar mejores cuestionarios para entender las experiencias y síntomas relacionados con la salud debido a tener HSIL o estar recibiendo tratamiento para HSIL. Este conocimiento quizá pueda ayudar a la gente a tomar decisiones en el futuro con respecto al tratamiento de HSIL. Usted recibirá $50 y una compensación por transporte y por su tiempo y esfuerzo una vez haga la entrevista. Si hace la entrevista por teléfono, tendremos que pedirle su dirección. Escribiremos la dirección en el sobre que le enviaremos con un giro postal de $50 y una carta de agradecimiento. No se registrará su dirección en ninguna otra parte.

***¿Esto es privado?***

Sí. **NO** se recolectarán nombres o información de contacto ni se archivarán o aparecerán en ningún dato o informe de investigación.

***¿Más preguntas?***

Nuestro personal del estudio tendrá el placer de contestar cualquier otra pregunta. Puede contactar a nuestro personal del estudio al: (**646) 888-0123,** para solicitar una cita con el Dr. Thomas Atkinson, del Department of Psychiatry & Behavioral Sciences (departamento de psiquiatría y ciencias conductuales) al: (**646) 888-0089**. Si desea hablar con una persona no médico para obtener más información sobre la participación en la investigación, los derechos de los pacientes en investigación o lesiones relacionadas con la investigación, llame a Jorge Capote, RN, Representante de pacientes, al número: **(212) 639-8254**.

***¡Le agradecemos por el tiempo que pasó informándose sobre nuestro estudio!***

## APPENDIX III: MONEY ORDER LETTER – ENGLISH

Hello,

Please find the enclosed money order as a ‘Thank You!’ for your time and effort spent completing the phone interview.

Sincerely,

Thomas Atkinson, Ph.D.

646-888-0089

## APPENDIX IV: MONEY ORDER LETTER – SPANISH

Hola,

Adjunto giro postal en “agradecimiento” por su tiempo y esfuerzo respondiendo la entrevista telefónica.

Atentamente,

Thomas Atkinson, Ph.D.

646-888-0089

## APPENDIX V: MEASURE LETTER – ENGLISH

Hello,

Please find the attached **ANCHOR ANAL HSIL HEALTH-RELATED QUALITY OF LIFE INDEX.**

We ask that you have this document with you at the time of your scheduled appointment and that you do not complete it before then. It is important for the interviewer to guide you through the questionnaire during the interview.

Your appointment is scheduled for:

Thank you for your participation!

## APPENDIX VI: MEASURE LETTER – SPANISH

Hola,

Adjuntamos **el ÍNDICE DE CALIDAD DE VIDA RELACIONADO CON LA SALUD PARA LESIONES EPITELIALES ESCAMOSAS ANALES DE ALTO GRADO DE ANCHOR (investigación de resultados para lesiones epiteliales escamosas de alto grado de cáncer anal)**.

Le pedimos que traiga este documento con usted para la cita que hemos programado y que no lo rellene antes de la cita. Es importante que obtenga asesoramiento de parte del entrevistador para rellenar el cuestionario durante la entrevista.

Su cita está programada para:

¡Le agradecemos por su participación!

## APPENDIX VII: COGNITIVE INTERVIEW SCRIPT – ENGLISH

### Introduction (Read to Participant)

- *It is important to understand the experiences of people who are diagnosed with Anal HSIL (pre-cancer lesion in the anus) (and any treatments they receive – IF APPLICABLE). That is why we are asking for your help today. We would like you to answer some questions for the next hour. We will be asking you to use some of the new questions we are developing, and then to tell us your experiences answering these questions, such as how easy or difficult the questions were to answer. Some of these questions will ask you about your symptoms related to Anal HSIL (and treatment – IF APPLICABLE). Some questions will ask about how Anal HSIL (and treatment – IF APPLICABLE) has impacted parts of your everyday life. With your help, we will be able to have a better understanding of what people who have Anal HSIL are experiencing.*
- *The information that you provide today will be used for research purposes, and will help people in the future.*

**ANCHOR ANAL HSIL HEALTH-RELATED QUALITY OF LIFE INDEX---DRAFT 2015v.7**

Below is a list of statements that other people diagnosed with anal HSIL (pre-cancer lesion in the anus) and treated or actively monitored have said are important. Please check the box to select your answer based on your experiences in **the past 7 days**. If you have **ANY** trouble selecting a response for any statement or find something hard to understand, please check the box in the *Check if Difficult to Understand* column for that statement. Please let me know when you have completed each of the three sections (Physical Symptoms, Physical Impacts, Psychological Symptoms).

| **PHYSICAL SYMPTOMS** | **Check if Not Applicable** | **Not at all 0** | **A little bit 1** | **Somewhat 2** | **Quite a bit 3** | **Very much 4** | **Difficult To Understand** |
|---|---|---|---|---|---|---|---|
| 1. I have anal pain | | | | | | | |
| 2. I have pain other than anal pain | | | | | | | |
| 3. I have pain during bowel movements | | | | | | | |
| 4. I have constipation | | | | | | | |
| 5. I have bleeding from the anus | | | | | | | |
| 6. I have itching in or around the anus | | | | | | | |
| 7. I have discharge (wetness) in my anal area | | | | | | | |
| 8. I have burning sensations in the anal area | | | | | | | |
| 9. I have urgency for bowel movements | | | | | | | |
| **PHYSICAL IMPACTS** | **Check if Not Applicable** | **Not at all 0** | **A little bit 1** | **Somewhat 2** | **Quite a bit 3** | **Very much 4** | **Difficult To Understand** |
| 10. I have problems with my physical ability to move around | | | | | | | |
| 11. I have problems with sitting | | | | | | | |
| 12. I have problems completing daily household chores (e.g., cleaning, cooking, laundry, house maintenance) | | | | | | | |
| 13. I have problems taking care of myself (e.g., bathing, dressing, shaving) | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 14. I have problems participating in leisure activities (e.g., watching television, relaxing) | | | | | | | |
| 15. I have problems participating in social activities (e.g., going out to eat, visiting friends) | | | | | | | |
| 16. I have problems with work productivity | | | | | | | |
| **PSYCHOLOGICAL SYMPTOMS** | **Check if Not Applicable** | **Not at all 0** | **A little bit 1** | **Somewhat 2** | **Quite a bit 3** | **Very much 4** | **Difficult To Understand** |
| 17. I have difficulty concentrating | | | | | | | |
| 18. I have a decreased enjoyment of anal sexual activity | | | | | | | |
| 19. I have a deceased enjoyment for any form of sexual activity other than anal sexual activity | | | | | | | |
| 20. I have a decreased desire for anal sexual activity | | | | | | | |
| 21. I have decreased desire for forms of sexual activity other than anal sexual activity | | | | | | | |
| 22. I am worried about my condition getting worse | | | | | | | |
| 23. I have anxiety | | | | | | | |
| 24. I have depression | | | | | | | |
| 25. I have problems with my intimate relationships | | | | | | | |

*Now let's quickly go through and have you tell me what your responses were to each of the 25 items [RECORD RESPONSES ON YOUR FORM]. Please let me know if you checked off 'Difficult to Understand' or 'Not Applicable' for any of the items.*

**Cognitive Interviewing Probes – General**

*First, for the statements that you responded to, was it easy to answer….*

- ○ All of the time
- ○ Most of the time
- ○ Some of the time
- ○ None of the time

*Were there any problems that made it difficult for you to answer the survey in general? If so, what were they?*

*Now let's go back and discuss any of those areas where you indicated that the statement was hard to understand. Putting aside issues that you have already told me about, what were the issues or problems that came up for you in those places?*

(Some of the issues raised during this portion may probe specific issues that we are targeting, please make note of these to work toward not repeating these issues again in the interview)

**Cognitive Interviewing Probes – Instructions**

Did you have any problems in understanding the instructions? If so, please describe these problems.

> *Below is a list of statements that other people diagnosed with anal HSIL and treated or actively monitored have said are important. Please check the box to select your answer based on your experiences in* ***the past 7 days****.*

What does the word experiences mean to you as it is used in these instructions? Is there another word or phrase that you would prefer that we use?

**Cognitive Interviewing Probes – Question-Specific**

You were asked about PAIN as a possible symptom related to your Anal HSIL. Do you experience PAIN that is separate from ANAL PAIN or PAIN DURING BOWEL MOVEMENTS?

> If so, how is the PAIN you experience different from ANAL PAIN or PAIN DURING BOWEL MOVEMENTS? Do you believe we should ask about all three types of PAIN?

What does ITCHING IN OR AROUND THE ANUS mean to you as it was used in this statement? Do you feel that ITCHING IN and ITCHING AROUND should be two separate statements?

*If patient experiences DISCHARGE (WETNESS):*

Which of the words DISCHARGE (WETNESS) do you prefer to describe this experience? Is there another word or phrase that you feel would better describe this experience?

What does BURNING SENSATION mean to you as it was used in this statement? Is there another word or phrase that you feel would better describe this experience?

What does PHYSICAL ABILITY TO MOVE AROUND mean to you as it was used in this statement? Is there another word or phrase that you feel would better describe this experience? If you were to choose between "moverse" and "movilizarse," which word would you prefer?

What does PROBLEMS WITH SITTING mean to you as it was used in this statement? Is there another word or phrase that you feel would better describe this experience? Would you prefer that we use "difficulty" sitting?

What does DAILY HOUSEHOLD CHORES (CLEANING, COOKING, LAUNDRY, HOUSE MAINTENANCE) mean to you as it was used in this statement? Are there other examples that you feel would be better to describe this experience?

What does PROBLEMS TAKING CARE OF MYSELF (BATHING, DRESSING, SHAVING, ETC.) mean to you as it was used in this statement? Are there other examples that you feel would be better to describe this experience?

What does PROBLEMS PARTICIPATING IN LEISURE ACTIVITIES (WATCHING TELEVISION, RELAXING) mean to you as it was used in this statement? Do you have any difficulty with the word "leisure"? Would you prefer that we use the phrase "activities you complete in your free time"? Are there other examples that you feel would be better to describe this experience?

What does PROBLEMS PARTICIPATING IN SOCIAL ACTIVITIES (GOING OUT TO EAT, VISITING FRIENDS) mean to you as it was used in this statement? Are there other examples that you feel would be better to describe this experience?

Do you feel that LEISURE ACTIVITIES and SOCIAL ACTIVITIES are both important to ask about? If you could be asked about just one of these, which would you select? Why?

What does PROBLEMS WITH WORK PRODUCTIVITY mean to you as it was used in this statement? [ASK IF PARTICIPANT NOT WORKING] Is there another word or phrase that you feel would better describe this experience?

What does DIFFICULTY CONCENTRATING mean to you as it was used in this statement?

What does DECREASED ENJOYMENT OF ANAL SEXUAL ACTIVITY mean to you as it was used in this statement?

> Would you prefer that we used "physical enjoyment" rather than "enjoyment" to ask about this experience?
>
> How is this different from DECREASED ENJOYMENT FOR OTHER FORMS OF SEXUAL ACTIVITY? Do you feel it is necessary to ask about both of these concepts? If you could be asked about just one of these, which would you select? Why?

What does DECREASED DESIRE FOR ANAL SEXUAL ACTIVITY mean to you as it was used in this statement?

> How is this different from DECREASED DESIRE FOR OTHER FORMS OF SEXUAL ACTIVITY? Do you feel it is necessary to ask about both of these concepts? If you could be asked about just one of these, which would you select? Why?

What does I AM WORRIED ABOUT MY CONDITION GETTING WORSE mean to you as it was used in this question?

What does INTIMATE RELATIONSHIPS mean to you as it was used in this question?

Would you prefer if we asked about "emotional closeness with others" rather than "intimate relationships"?

**Cognitive Interviewing Probes – Comprehensibility of the response scale**

Overall, how difficult was it to select an answer for statements asking you to select not at all, a little bit, somewhat, quite a bit, very much? [GIVE EXAMPLE FROM QUESTIONNAIRE]

- ○ NOT AT ALL difficult
- ○ A LITTLE difficult
- ○ SOMEWHAT difficult
- ○ VERY difficult

*For the following, you should find an item that the patient responded with a 2 and determine how that differed from a 1 or 3 response. Similarly, you should find an item that the patient responded with a 3 and determine how that differed from a 2 or 4 response.*

> You answered (2). How did you come up with that answer? What makes that a better answer than (x+1)? What makes (x) a better answer than (x-1)?
> You answered (3). How did you come up with that answer? What makes that a better answer than (x+1)? What makes (x) a better answer than (x-1)?

Were there any other words in the answer choices that were confusing or hard to understand? If so, which ones?

**Cognitive Interviewing Probes – Recall period**

How easy or difficult was it to think about your experiences over the last 7 days? Is there a better time period for considering your experiences?

**Summary Questions**

*Now that you have finished answering all the items, I would like to ask you a few final questions about the survey as a whole. Remember that we are only interested in improving our survey, so if something was confusing or hard to answer then make sure you tell us that, because that is exactly what we want to find out today.*

- *Did you find this interview difficult?*
- *Was the survey too long?*
- *Does any one survey statement stick out in your mind as being particularly difficult for you?*
- *Is there anything else you would like us to know about this questionnaire? Do you have any suggestions for improving it for others?*

## APPENDIX VIII: COGNITIVE INTERVIEW SCRIPT – SPANISH

### Introducción (léale al participante)

*Es importante entender las experiencias de las personas diagnosticadas con HSIL anal (lesiones precancerosas en el ano) (y cualquier tratamiento que reciban – SI APLICA). Por eso le estamos pidiendo ayuda hoy. Nos gustaría que conteste algunas preguntas durante la próxima hora. Le pediremos que conteste algunas de las preguntas nuevas que estamos desarrollando y que luego nos cuente sus experiencias contestando estas preguntas, como por ejemplo, qué tan fácil o difícil fue contestarlas. Algunas preguntas tendrán que ver con los síntomas relacionados con HSIL anal (y tratamiento – SI APLICA). Otras tendrán que ver con la manera en que HSIL anal (y tratamiento – SI APLICA) ha impactado aspectos de su vida diaria. Usted nos ayudará a entender mejor lo que experimentan las personas con HSIL anal. La información que nos de hoy se utilizará en investigación, y ayudará a otras personas en el futuro.*

## ÍNDICE DE SÍNTOMAS RELACIONADOS CON LA SALUD ANCHOR

A continuación presentamos una lista de afirmaciones que otras personas diagnosticadas con HSIL (lesión precancerosa en el ano) y que han sido tratadas o monitoreadas activamente han dicho que son importantes. Por favor seleccione la casilla con su respuesta basándose en sus experiencias en **los últimos 7 días**.
Si tiene **ALGÚN** problema seleccionando una respuesta o le cuesta contestar algo, por favor seleccione la casilla en la columna que dice, *Difícil de entender.* Déjeme saber cuando haya terminado cada una de estas secciones (Síntomas físicos, Impactos físicos, Síntomas psicológicos).

| **SÍNTOMAS FÍSICOS** | **Escoja si no aplica** | **Para nada 0** | **Un poco 1** | **Algo 2** | **Bastante 3** | **Muchísimo 4** | **Difícil de entender** |
|---|---|---|---|---|---|---|---|
| 1. Tengo dolor anal | | | | | | | |
| 2. Tengo dolor pero no en el área anal | | | | | | | |
| 3. Tengo dolor cuando entro al baño a defecar | | | | | | | |
| 4. Tengo estreñimiento | | | | | | | |
| 5. Tengo sangrado del ano | | | | | | | |
| 6. Tengo picazón en el ano o alrededor del ano | | | | | | | |
| 7. Tengo una secreción (mojado) en el área anal | | | | | | | |
| 8. Tengo sensación de ardor en el área anal | | | | | | | |
| 9. Siento urgencia de entrar al baño a defecar | | | | | | | |
| **IMPACTOS FÍSICOS** | **Escoja si no aplica** | **Para nada 0** | **Un poco 1** | **Algo 2** | **Bastante 3** | **Muchísimo 4** | **Difícil de entender** |
| 10. Tengo problemas con mi capacidad física para movilizarme | | | | | | | |
| 11. Tengo problemas para sentarme | | | | | | | |
| 12. Tengo problemas terminando las tareas de la casa (por ej., limpiar, cocinar, hacer la colada, llevar la casa) | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 13. Tengo problemas con mi arreglo personal diario (por ej., bañándome, vistiéndome, afeitándome) | | | | | | | |
| 14. Tengo problemas participando en actividades de ocio (por ej., mirar televisión, relajarme) | | | | | | | |
| 15. Tengo problemas participando en actividades sociales (por ej., salir a comer, visitar amigos) | | | | | | | |
| 16. Tengo problemas siendo productivo en el trabajo | | | | | | | |
| **SÍNTOMAS PSICOLÓGICOS** | **Escoja si no aplica** | **Para nada 0** | **Un poco 1** | **Algo 2** | **Bastante 3** | **Muchísimo 4** | **Difícil de entender** |
| 17. Tengo dificultad concentrándome | | | | | | | |
| 18. Me ha disminuido el placer de la actividad sexual anal | | | | | | | |
| 19. Me ha disminuido el placer de cualquier forma de actividad sexual diferente a la actividad sexual anal | | | | | | | |
| 20. Me ha disminuido el deseo por la actividad sexual anal | | | | | | | |
| 21. Me ha disminuido el deseo por formas de actividad sexual diferentes a la actividad sexual anal | | | | | | | |
| 22. Me preocupa que mi enfermedad empeore | | | | | | | |
| 23. Tengo ansiedad | | | | | | | |
| 24. Tengo depresión | | | | | | | |
| 25. Tengo problemas con mis relaciones íntimas | | | | | | | |

Ahora nos va a contar cuáles fueron sus respuestas para cada una de las 25 preguntas (REGISTRE LAS RESPUESTAS EN SU FORMULARIO). Por favor cuénteme si escogió "*Difícil de entender"* o "*No aplica"*.

**Sondeo de la entrevista cognitiva – General**

*Primero, para las cosas que contestó, fue fácil de contestar….*

- ○ Todo el tiempo
- ○ La mayoría del tiempo
- ○ Algunas veces
- ○ Nunca

*¿Hubo algún problema que hizo difícil contestar la encuesta en general? Si sí, ¿qué?*

*Ahora examinemos lo que le pareció difícil de entender. Olvidándose de las cosas que ya me ha contado, ¿cuáles fueron los problemas que surgieron en esos momentos?*

(Algunos de los asuntos planteados durante esta porción podrían hacer resaltar problemas específicos que forman parte de nuestro objetivo. Por favor tome nota de ellos para que no vuelvan a surgir durante la entrevista).

**Sondeo de la entrevista cognitiva – Instrucciones**

¿Tuvo algún problema entendiendo las instrucciones? Si sí, por favor describa estos problemas.

> *A continuación presentamos una lista de afirmaciones que otras personas diagnosticadas con HSIL (lesión precancerosa en el ano) y que han sido tratadas o monitoreadas activamente han dicho que son importantes. Por favor seleccione la casilla con su respuesta basándose en sus experiencias* ***en los últimos 7 días****.*

¿Qué significa para usted la palabra "experiencias" tal como se utiliza en estas instrucciones? ¿Preferiría que utilicemos alguna otra palabra o frase?

**Sondeo de la entrevista cognitiva – Preguntas específicas**

Le preguntaron sobre DOLOR como un síntoma posible relacionado con HSIL anal. ¿Experimenta DOLOR no vinculado con el DOLOR ANAL o DOLOR DURANTE LA DEFECACIÓN?

> Si respondió que sí, ¿el DOLOR que usted siente es diferente al DOLOR ANAL o DOLOR DURANTE LA DEFECACIÓN? ¿Le parece que debemos preguntar sobre los tres tipos de DOLOR?

¿Qué quiere decir para usted PICAZÓN EN EL ANO O ALREDEDOR DEL ANO según se preguntó en esta afirmación? ¿Piensa que PICAZÓN EN y PICAZÓN ALREDEDOR deberían ser dos afirmaciones separadas?

*Si el paciente experimenta SECRECIÓN (MOJADO):*

> ¿Cuál palabra SECRECIÓN (MOJADO) prefiere para describir esta experiencia? ¿Existe otra palabra o frase que piensa que describiría mejor esta experiencia?

¿Qué significa para usted SENSACIÓN DE ARDOR según se usó en esta afirmación? ¿Existe otra palabra o frase que piensa que describiría mejor esta experiencia?

¿Qué significa para usted LA CAPACIDAD FÍSICA PARA MOVILIZARSE en esta afirmación? ¿Existe otra palabra o frase que piensa que describiría mejor esta experiencia? Si tuviera que elegir entre "moverse" o "movilizarse", ¿cuál palabra elegiría?

¿Qué significa para usted TENER PROBLEMAS PARA SENTARSE en esta afirmación? ¿Existe otra palabra o frase que piensa que describiría mejor esta experiencia? ¿Preferiría que se usara la frase "dificultad para sentarse"?

¿Qué significa para usted TAREAS DE LA CASA DIARIAS (LIMPIAR, COCINAR, HACER LA COLADA, LLEVAR LA CASA) según se usó en esta afirmación? ¿Hay otros ejemplos que piensa que funcionarían mejor para describir esta experiencia?

¿Qué significa para usted PROBLEMAS PERSONALES DIARIOS (BAÑÁNDOSE, VISTIÉNDOSE, AFEITÁNDOSE, ETC.) según se usó en esta afirmación? ¿Hay otros ejemplos que piensa que funcionarían mejor para describir esta experiencia?

¿Qué significa para usted PROBLEMAS PARTICIPANDO EN ACTIVIDADES DE OCIO (MIRANDO TELEVISIÓN, RELAJÁNDOSE) según se usó en esta afirmación? ¿Le plantea alguna dificultad la palabra "ocio"? ¿Preferiría que se utilice la frase "actividades que realiza en su tiempo libre"? ¿Hay otros ejemplos que piensa que funcionarían mejor para describir esta experiencia?

¿Qué significa para usted PROBLEMAS PARTICIPANDO EN ACTIVIDADES SOCIALES (SALIR A COMER, VISITAR AMIGOS) según se usó en esta afirmación? ¿Hay otros ejemplos que piensa que funcionarían mejor para describir esta experiencia?

> ¿Piensa que es importante preguntar sobre ACTIVIDADES DE OCIO y ACTIVIDADES SOCIALES? Si se le preguntara tan solo una de ellas, ¿cuál seleccionaría? ¿Por qué?

¿Qué significa para usted PROBLEMAS CON LA PRODUCTIVIDAD EN EL TRABAJO según se usó en esta afirmación? (PREGUNTE SI EL PARTICIPANTE NO ESTÁ TRABAJANDO) ¿Hay alguna otra palabra o frase que usted cree que describiría mejor esta experiencia?

¿Qué significa para usted DIFICULTAD CONCENTRÁNDOSE según se usó en esta afirmación?

¿Qué significa para usted DISMINUCIÓN DE PLACER DE LA ACTIVIDAD SEXUAL ANAL según se usó en esta afirmación?

> ¿Preferiría que se utilice la frase "placer físico" en vez de "placer" al preguntar sobre esta experiencia?
>
> ¿En qué se diferencia de DISMINUCIÓN DE PLACER POR OTRAS FORMAS DE ACTIVIDAD SEXUAL? ¿Piensa que es necesario que se le pregunte sobre ambos conceptos? Si se le preguntara tan solo uno de ellos, ¿cuál seleccionaría? ¿Por qué?

¿Qué significa para usted DISMINUCIÓN DE DESEO POR ACTIVIDAD SEXUAL ANAL según se usó en esta afirmación?

> ¿En qué se diferencia de DISMINUCIÓN DE DESEO POR OTRAS FORMAS DE ACTIVIDAD SEXUAL? ¿Piensa que es necesario que se le pregunte sobre ambos conceptos? Si se le preguntara tan solo uno de ellos, ¿cuál seleccionaría? ¿Por qué?

¿Qué significa para usted ESTOY PREOCUPADO QUE MI ENFERMEDAD EMPEORE según se usó en esta pregunta?

¿Qué significa para usted RELACIONES ÍNTIMAS según se usó en esta pregunta?

¿Preferiría que preguntásemos sobre la "intimidad afectiva con otras personas" en vez de "relaciones íntimas"?

**Sondeo de la entrevista cognitiva – Comprensión de la escala de respuesta**

En general, ¿qué tan difícil fue seleccionar respuestas para las afirmaciones que le pedían que seleccionara, para nada, un poco, algo, bastante, mucho? (DE EJEMPLOS DEL CUESTIONARIO)

- PARA NADA difícil
- UN POCO difícil
- ALGO difícil
- MUY difícil

*Para lo siguiente debe encontrar un ítem para el que el paciente contestó con un 2 y determinar de qué manera difirió de una respuesta 1 o 3. También debe encontrar un ítem para el que el paciente contestó con un 3 y determinar de qué manera difirió de una respuesta 2 o 4.*

> Usted contestó (2). ¿Cómo llegó a esa respuesta? ¿Por qué es una mejor respuesta que (x+1)? ¿Por qué (x) es una mejor respuesta que (x-1)?

Usted contestó (3). ¿Cómo llegó a esa respuesta? ¿Por qué es una mejor respuesta que (x+1)? ¿Por qué (x) es una mejor respuesta que (x-1)?

¿Hubo algunas otras palabras en las opciones de respuesta que eran confusas o difíciles de entender? Si sí, ¿cuáles?

**Sondeo de la entrevista cognitiva – Período recordatorio**

¿Qué tan fácil o difícil fue pensar en sus experiencias en los últimos 7 días? ¿Existe un mejor período de tiempo para considerar sus experiencias?

**Respuestas de resumen**

*Ahora que ha respondido todo, me gustaría hacerle un par de preguntas finales sobre la entrevista en su totalidad. Recuerde que tan solo nos interesa mejorar la encuesta, por lo que si algo le resultó confuso o difícil de contestar asegúrese de decirlo—eso es exactamente lo que queremos averiguar.*

- *¿Le pareció difícil esta entrevista?*
- *¿Le pareció que la entrevista fue demasiado larga?*
- *¿Alguna afirmación en la encuesta sobresalió por ser particularmente difícil para usted?*
- *¿Hay algo más que le gustaría que supiéramos sobre este cuestionario? ¿Tiene alguna sugerencia para mejorarlo para otras personas?*

## APPENDIX IX: DEMOGRAPHIC SHEET – ENGLISH

DATE: ____/____/_____

1. Age: _____ years

2. What gender do you identify with? (Please check appropriate boxes)

☐ Male/Man (1)
☐ Female/Woman (2)
☐ Transgender man/Transman/Female to male (3)
☐ Transgender woman/Transwoman/Male to female (4)
☐ Genderqueer/Gender nonconforming (5)
☐ Something else (6)
☐ Decline to answer (9)

3. Do you identify as Hispanic, Latino, or Spanish?

☐ No (0)
☐ Yes (1), Nationality: _____
☐ Don't know (8)
☐ Decline to answer (9)

4. What racial group do you most identify with?

☐ White (1)
☐ Black or African American (2)
☐ Asian or Pacific Islander (3)
☐ American Indian or Alaskan Native (4)
☐ Other (5), please specify: _____
☐ Decline to answer (9)

5. What is your highest education level?

☐ Never attended school (1)
☐ Elementary school (2)
☐ Some high school (3)
☐ GED (4)
☐ High school graduate (5)
☐ Some college or technical school (6)
☐ College graduate (7)
☐ Graduate or professional school
☐ Decline to answer

## APPENDIX X: DEMOGRAPHIC SHEET – SPANISH

FECHA: ____/____/_____

1. Edad: _____ años

2. ¿Con qué género se identifica? (Seleccione las casillas correspondientes)

- ☐ Masculino/Hombre (1)
- ☐ Femenino/Mujer (2)
- ☐ Hombre transgénero/Hombre trans/Femenino a masculino (3)
- ☐ Mujer transgénero/Mujer trans/Masculino a femenino (4)
- ☐ Genderqueer (una persona que no se adscribe a distinciones convencionales de género sino que no se identifica con ninguna o que se identifica con ambas o con una combinación de masculino y femenino)/no conforme con el género (una persona cuya identidad o expresión de género actual no obedecen a las expectativas sociales basadas en el sexo que se les asignó al nacer) (5)
- ☐ Otro (6)
- ☐ Se negó a contestar

3. ¿Se identifica como hispano, latino o español?

- ☐ No (0)
- ☐ Sí (1), nacionalidad: _____
- ☐ No sabe (8)
- ☐ Se negó a contestar

4. ¿Con qué grupo racial se identifica más?

- ☐ Blanco (1)
- ☐ Negro o afroamericano (2)
- ☐ Asiático o de las islas del Pacífico (3)
- ☐ Indígena americano o nativo de Alaska (4)
- ☐ Otro: (5), por favor especifique: _____
- ☐ Se negó a contestar (9)

5. ¿Cuál es su nivel de educación más alto?

- ☐ Nunca asistió a la escuela (1)
- ☐ Escuela elemental (2)
- ☐ Algo de secundaria (3)
- ☐ GED (o diploma de equivalencia de secundaria) (4)
- ☐ Graduado de secundaria (5)
- ☐ Algo de universidad o educación técnica (6)
- ☐ Graduado de universidad (7)
- ☐ Postgrado
- ☐ Se negó a contesta

## APPENDIX XI: ANCHOR HEALTH-RELATED SYMPTOM INDEX – ENGLISH

Below is a list of statements that other people diagnosed with anal HSIL (pre-cancer lesion in the anus) and treated or actively monitored have said are important. Please check the box to select your answer based on your experiences in **the past 7 days**.

| **PHYSICAL SYMPTOMS** | **Check if Not Applicable** | **Not at all 0** | **A little bit 1** | **Somewhat 2** | **Quite a bit 3** | **Very much 4** | **Difficult to Understand** |
|---|---|---|---|---|---|---|---|
| 1. I have anal pain | | | | | | | |
| 2. I have pain other than anal pain | | | | | | | |
| 3. I have pain during bowel movements | | | | | | | |
| 4. I have constipation | | | | | | | |
| 5. I have bleeding from the anus | | | | | | | |
| 6. I have itching in or around the anus | | | | | | | |
| 7. I have discharge (wetness) in my anal area | | | | | | | |
| 8. I have burning sensations in the anal area | | | | | | | |
| 9. I have urgency for bowel movements | | | | | | | |
| **PHYSICAL IMPACTS** | **Check if Not Applicable** | **Not at all 0** | **A little bit 1** | **Somewhat 2** | **Quite a bit 3** | **Very much 4** | **Difficult to Understand** |
| 10. I have problems with my physical ability to move around | | | | | | | |
| 11. I have problems with sitting | | | | | | | |
| 12. I have problems completing daily household chores (e.g., cleaning, cooking, laundry, house maintenance) | | | | | | | |
| 13. I have problems taking care of myself (e.g., bathing, dressing, shaving) | | | | | | | |
| 14. I have problems participating in leisure activities (e.g., watching television, relaxing) | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 15. I have problems participating in social activities (e.g., going out to eat, visiting friends) | | | | | | | |
| 16. I have problems with work productivity | | | | | | | |
| **PSYCHOLOGICAL SYMPTOMS** | **Check if Not Applicable** | **Not at all 0** | **A little bit 1** | **Somewhat 2** | **Quite a bit 3** | **Very much 4** | **Difficult to Understand** |
| 17. I have difficulty concentrating | | | | | | | |
| 18. I have a decreased enjoyment of anal sexual activity | | | | | | | |
| 19. I have a deceased enjoyment for any form of sexual activity other than anal sexual activity | | | | | | | |
| 20. I have a decreased desire for anal sexual activity | | | | | | | |
| 21. I have decreased desire for forms of sexual activity other than anal sexual activity | | | | | | | |
| 22. I am worried about my condition getting worse | | | | | | | |
| 23. I have anxiety | | | | | | | |
| 24. I have depression | | | | | | | |
| 25. I have problems with my intimate relationships | | | | | | | |

## APPENDIX XII: ANCHOR HEALTH-RELATED SYMPTOM INDEX – SPANISH

## ÍNDICE DE SÍNTOMAS RELACIONADOS CON LA SALUD ANCHOR

A continuación presentamos una lista de afirmaciones que otras personas diagnosticadas con HSIL (lesión precancerosa en el ano) y que han sido tratadas o monitoreadas activamente han dicho que son importantes. Por favor seleccione la casilla con su respuesta basándose en sus experiencias en **los últimos 7 días**.

| **SÍNTOMAS FÍSICOS** | **Escoja si no aplica** | **Para nada 0** | **Un poco 1** | **Algo 2** | **Bastante 3** | **Muchísimo 4** | **Difícil de entender** |
|---|---|---|---|---|---|---|---|
| 1. Tengo dolor anal | | | | | | | |
| 2. Tengo dolor pero no en el área anal | | | | | | | |
| 3. Tengo dolor cuando entro al baño a defecar | | | | | | | |
| 4. Tengo estreñimiento | | | | | | | |
| 5. Tengo sangrado del ano | | | | | | | |
| 6. Tengo picazón en el ano o alrededor del ano | | | | | | | |
| 7. Tengo una secreción (mojado) en el área anal | | | | | | | |
| 8. Tengo sensación de ardor en el área anal | | | | | | | |
| 9. Siento urgencia de entrar al baño a defecar | | | | | | | |
| **IMPACTOS FÍSICOS** | **Escoja si no aplica** | **Para nada 0** | **Un poco 1** | **Algo 2** | **Bastante 3** | **Muchísimo 4** | **Difícil de entender** |
| 10. Tengo problemas con mi capacidad física para movilizarme | | | | | | | |
| 11. Tengo problemas para sentarme | | | | | | | |
| 12. Tengo problemas terminando las tareas de la casa (por ej., limpiar, cocinar, hacer la colada, administrar la casa) | | | | | | | |
| 13. Tengo problemas con mi arreglo personal diario (por ej., bañándome, vistiéndome, afeitándome) | | | | | | | |
| 14. Tengo problemas participando en actividades de ocio (por ej., mirar televisión, relajarme) | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 15. Tengo problemas participando en actividades sociales (por ej., salir a comer, visitar amigos) | | | | | | | |
| 16. Tengo problemas siendo productivo en el trabajo | | | | | | | |
| **SÍNTOMAS PSICOLÓGICOS** | **Escoja si no aplica** | **Para nada 0** | **Un poco 1** | **Algo 2** | **Bastante 3** | **Muchísimo 4** | **Difícil de entender** |
| 17. Tengo dificultad concentrándome | | | | | | | |
| 18. Me ha disminuido el placer de la actividad sexual anal | | | | | | | |
| 19. Me ha disminuido el placer de cualquier forma de actividad sexual diferente a la actividad sexual anal | | | | | | | |
| 20. Me ha disminuido el deseo por la actividad sexual anal | | | | | | | |
| 21. Me ha disminuido el deseo por formas de actividad sexual diferentes a la actividad sexual anal | | | | | | | |
| 22. Me preocupa que mi enfermedad empeore | | | | | | | |
| 23. Tengo ansiedad | | | | | | | |
| 24. Tengo depresión | | | | | | | |
| 25. Tengo problemas con mis relaciones íntimas | | | | | | | |

## APPENDIX XIII: LANGUAGE SCREENER – ENGLISH

*Language Proficiency and Preference*

How well do you speak English?

☐ Very Well

☐ Well

☐ Not well

☐ Not at all

2. What language do you prefer for health care?

(specify the language) _____

(If English, **NOT ELIGIBLE)**
(If Spanish, **ELIGIBLE)**

## APPENDIX XIV: LANGUAGE SCREENER – SPANISH

*Dominio y preferencia de idioma*

1. ¿Qué tan bien habla el inglés?

   ☐ Muy bien

   ☐ Bien

   ☐ No bien

   ☐ Para nada bien

2. ¿En qué idioma prefiere comunicarse pare recibir su cuidado médico?

   (Especifique el idioma) _____

(Si eligió inglés, **NO ES ELEGIBLE**)
(Si eligió español, **ES ELEGIBLE**)