Verbal Consent Form Template

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

DIRECTIONS FOR INTERVIEWER/CONSENTING PROFESSIONAL ONCE REFERRED ANCHOR PARTICIPANT CALLS:

"Hello! My name is _(consenting professional)____ and I am the study staff at Memorial Sloan Kettering Cancer Center in New York City. Thank you for contacting us regarding our clinical study „**Validation of a Health-Related Symptom Index for Persons Diagnosed with and either Treated or Monitored for Anal High-Grade Squamous Intraepithelial Lesions (HSIL).** You are being asked to take part in this study because you are participating in the ANCHOR study and you have been diagnosed with anal HSIL, also called "anal pre-cancer lesions."

Our conversation will take about „15" minutes, are you interested in learning more?

Can you please provide me the code at the top of the Study Information Sheet that you were given:

_____/_____/_____/_____ - _____ - _____

If no: When would be a good time for me to call? _____
If yes: continue with the call

A clinical research study is completely voluntary and includes only people who choose to take part. Please take your time to make your decision about taking part. If at any time you have questions, please feel free to ask me for further explanation.

During our discussion we will cover information about the research study. Once you understand the study, its risks, and its benefits, and we have discussed your questions, you will be asked if you want to take part.

Do you have any questions so far?

Would you like to hear about our Study?

- **NO- Thank the individual for their time and end the call.**
- **YES- Continue with next section, but first : (OPTION 1:** Ask if „Do you have the hard copy of the informed consent, sent to you in the informational packet, available to use as a guide?"; **OPTION 2**: If no summary mailed ahead of time, let them know that „After our conversation, we will mail you a summary of the study."**)**

Today"s date is _____ **(MM/DD/YYYY)**. My name is _____ and I am verbally consenting you to participate in the study, "_____".

Can you please state your full name? _____
(Please ask them to spell)

Study Information:
DIRECTIONS FOR WRITING SCRIPT SECTION: Briefly describe below the specific study and the participant's potential role. This must include, but not limited to what we are trying to learn more about, how many participants

will take part and duration, what will happen to participant (before, during, after) (refer to hard copy of consent's images/calendars, if previously mailed), and that they can stop or be stopped at any time:

The purpose of this study is to finalize development of a questionnaire that measures health-related symptoms and concerns for persons diagnosed with, and either treated or monitored for, analanal pre-cancer lesions. You have been referred to this study because you are HIV+ and have been treated or monitored for anal pre-cancer lesion/s and have consented to the ANCHOR study.

About 100 people will take part in this study at MSKCC.

We will ask you to complete some questionnaires over the phone with our study staff. The questions ask about your physical and emotional well-being related to your anal pre-cancer lesion/s. We will also ask you a few questions about your demographic such as age, gender, and race. These questionnaires take about 25 minutes to complete. We will then contact you about 7-10 days later by phone and ask you to complete most of the same questionnaires again. These take about 30 minutes to complete. Once complete, your participation in the study will be over.

After you have finished the study, it is possible that research staff may contact you to clarify a comment or answer you had given.

Do you have any questions about this study and our discussion so far?

Would you like to hear more so you can decide whether to take part?:

- **NO- Thank the individual for their time and end the call.**
- **YES- Continue with next section.**

DIRECTIONS FOR WRITING SCRIPT SECTION: Briefly describe the Risks, Benefits, Alternatives, and Rights of potential participant; see following suggestion:

There are no physical risks involved with this study. It is possible that some of the questions you will be asked could make you feel uncomfortable. You may decline to answer any questions presented, and you may ask any questions about this study at any time. Please tell the study doctor or study staff if you feel uncomfortable or upset during your participation in this study. If you report a high level of distress related to symptoms we ask you about, we will encourage you to speak with your study doctor for help with these symptoms.

You may not benefit directly from the study. However, your responses may help researchers understand how the symptoms from anal pre-cancer lesion/s and the treatment of anal pre-cancer lesion/s affect patients.

The choice to take part in this study or not is yours. Make your choice based on what we have explained to you and what you have read about the study. This study does not involve any treatment for your anal pre-cancer lesion/s. Due to the nature of this study, your alternative is to not participate. Your participation in this study will not impact your medical care.

Do you have any questions about this study and our discussion so far?

DIRECTIONS FOR WRITING SCRIPT SECTION: Briefly describe Potential Costs/Injury and Privacy aspects of the study; see following suggestion:

There are no costs to take part in this study. For your time and effort, you will receive $100 money order by mail upon completing **both** sets of questionnaires. You will not receive this money if you only complete only 1 set of the questionnaires.

In case of injury from study related procedures, you will get treatment as a result of taking part in this study, but you and/or your health plan will be charged for this treatment. You do not lose any of your

legal rights to seek payment by verbally consenting to participate on this study. The study will not pay for the medical treatment.

It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. We cannot use any of your health information for research unless you tell us that we can. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Access to your medical information (e.g. entire medical/research record and NYS requirement for disclosure of HIV-related information) will be limited to those individuals involved with this study, our Institutional Review Board/Privacy Board whom reviewed this new study to make sure that your rights and welfare are protected, staff of the hospital's clinical research teams, our Data Safety Monitoring Board, and the Quality Assurance Committee. In addition and if necessary, the National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, other agencies responsible for oversight and the sponsor of this study Memorial Sloan-Kettering Cancer Center and members of the research teams at participating sites would have access. Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital. Some of the people or organizations I mentioned may not be subject to privacy laws. This means they could share your information again.

Please remember if you agree to take part in this study, it means you are giving us permission to share your protected health information. We can only share it with the people/organizations I just described. If you withdraw from the study at any time we cannot use or share anymore of your research data. If we have already used or shared your information, it cannot be taken back.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Do you have any questions about this study or your participation?

You can talk to your study doctor about any questions or concerns you have about this study. Contact the study doctor, Tom Atkinson, PhD at 646-888-0089and/or your study contact Andrew Webb at 646-888-0045.
There are no known individual or institutional conflicts of interest for this study.
For a non-physician whom you may call for more information about the consent process, research patients" rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

Are you ready to decide whether or not to participate?

By verbally agreeing to take part in this study, you acknowledge that you understand and accept all of the information provided to you. Do you voluntarily agree to participate in this study? (Participants should state YES or NO) _____.

AFTER INTERVIEW, STATE PARTICIPANT'S NAME, DATE, AND INTERVIEWER'S NAME ON THE FORM.

_____ _____
PARTICIPANT NAME DATE: MM/DD/YYYY

_____

SIGNATURE OF THE CONSENTING INDIVIDUAL

_____

NAME (PRINT) OF THE CONSENTING INDIVIDUAL