#### Attachment A

## National Health and Nutrition Examination Survey (NHANES) Oral HPV Follow-up Feasibility Study Adults 18-69 Years Old

OMB no. 0920-0950 Expires: 11/30/2016

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### NHANES Oral HPV Follow-up: Self-Collection Feasibility Study (18-69 years)

<u>Eligibility</u>: All NHANES participants 18-69 years who provided a baseline oral HPV specimen in the mobile examination center (MEC), beginning in 2015, are eligible. The maximum number of respondents would be 225.

<u>Informed Consent</u>: Written informed consent will be obtained as part of the regular National Health and Nutrition Examination Survey (NHANES) consent process for the examination in the Mobile Examination Center (MEC). It will be described as one of the follow-up activities on the Health Measurements list.

Exclusion Criteria: There are no exclusion criteria for this study.

<u>Specimen Collection:</u> A kit containing materials for oral rinse self-collection will be sent to eligible participant's homes six months from the time of the MEC visit. Instructions and a postage-paid return envelope will be included. The burden for specimen collection is estimated at 5 minutes.

Questionnaire: Eligible participants will also be asked to answer 9 questions on sexual behavior, tobacco and alcohol use. Questions are similar to those previously asked in the Mobile Examination Center. Respondents will have the option of answering the questions using a webbased Internet application, by telephone or with paper and pencil. The burden for responding to the questionnaire is estimated at 5 minutes.

<u>Report of Findings:</u> No report of findings will be provided. The specimens will not be tested for the HPV virus. Evaluations of oral rinse samples will be conducted for the quality and quantity of DNA, amount of endogenous retrovirus-3 (ERV-3), and amplifiability of the virus beta-globin gene.

# **Proposed Questionnaire**

# **Both Male and Female participants**

Ple	-	ths, how often did you drink any type of alcoholic beverage?  how many days per week or how many days per month or how many days ink?	
	NUMBER	days per week	
	OR		
	NUMBER	days per month	
	OR		
	NUMBER	days per year	
	□ NEVER		
2.	Do you now smol	ke cigarettes every day, some days, or not at all?	
	□ EVER	Y DAY (Go To 3.)	
	☐ SOME DAYS (Go To 3.)		
	$\square$ NOT A	AT ALL (Skip To 4.)	

3.	During the past 30 days, when you smoked, about how many cigarettes did {you/SP} usually smoke per day?
	NUMBER
4.	Smokeless tobacco products are placed in the mouth or nose and include chewing tobacco, snuff, snus, or dissolvables.
	During the past 30 days, including today, did {you/he/she} use any smokeless tobacco?
	(Please do not include nicotine replacement to help you stop smoking.)
	□Yes □ No
Quest	ions for Males Only
	xt questions are about your recent sexual history. <b>By sex, we mean</b> vaginal, oral, or anal sex. remember that your answers are strictly <b>confidential</b> .
5.	In the past 6 months, with how many women have you had any kind of sex?
	Please write a number or write zero for none.
	NUMBER
6.	In the past 6 months, with how many women have you had vaginal sex? Vaginal sex means your penis in her vagina.
	Please write a number or write zero for none.
	NUMBER
7	In the past 6 months, on how many women have you performed oral sex? Performing or

7. In the past 6 months, on how many women have you performed oral sex? Performing oral sex means your mouth on a woman's vagina or genitals.

Please write a number or write zero for none.

	NUMBER	
8.	In the past 6 months, with how many men have you had sex? By sex, we mean sexual contact with another man's penis or genitals.	
	Please write a number or write zero for none.	
	NUMBER	
9.	In the past 6 months, did you have any kind of sex with a person that you have never had sex with before?	
	□Yes □ No	
Quest	ions for Females Only	
The next questions are about your recent sexual history. <b>By sex, we mean</b> vaginal, oral, or anal sex. Please remember that your answers are strictly <b>confidential</b> .		
	1. In the past 6 months, with how many men have you had any kind of sex?	
	Please write a number or write zero for none.	
	NUMBER	
	2. In the past 6 months, with how many men have you had vaginal sex? Vaginal sex means a man's penis in your vagina.	
	Please write a number or write zero for none.	
	NUMBER	

oral sex means your mouth on a man's penis or genitals.
Please write a number or write zero for none.
NUMBER
4. In the past 6 months, with how many women have you had sex? By sex, we mean sexual contact with another woman's vagina or genitals.
Please write a number or write zero for none.
NUMBER
5. In the past 6 months, did you have any kind of sex with a person that you have neve had sex with before?
□Yes □ No

3. In the past 6 months, on how many men have you performed oral sex? Performing