Saliva Collection Protocol and Form OMB#: ####-### EXP.DATE: ##/#####

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 10 minutes for this questionnaire, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current, valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN:PRA (####-####).

Saliva Collection Instructions

This kit contains everything you will need to provide a sample of your saliva:

- 2 straws
- 2 small containers (pre-labeled)
- 1 re-sealable plastic bag with absorbent pad

We are asking you to collect two saliva samples over a single day, one in the morning and one in the evening. You should collect your first saliva sample as soon as you wake up (\$\sigma\$ sample) and collect the second saliva sample at night before you go to bed, at least 1 hour after eating but before brushing your teeth (\$\sigma\$.sample).

During a single day:

Use the two small containers marked with a $\mbox{\ensuremath{\mbox{$\m$

Use the small container marked with a to collect the second sample.

IMPORTANT NOTES

- ✓ Please record the time that you collect each sample.
- ✓ <u>Take the first sample as soon as you wake up!</u> It is okay to either wake up naturally or to an alarm clock, but you should not lie in bed and doze before you begin.
- ✓ Do not eat, drink, smoke or brush your teeth before collecting your morning

sample(🌣)

- ✓ Do not eat, drink, smoke or brush your teeth for 1 hour before collecting the Bedtime sample (்). If this cannot be avoided, rinse your mouth thoroughly with water at least 5 minutes before collecting the sample.
- ✓ Do not drink alcohol for 12 hours prior to collecting the samples.
- ✓ If your mouth is dry, do not use salivary stimulants such as chewing gum, lemon drops, sugar, or drink crystals such as Kool-Aid or Crystal Light prior to collecting the samples.
- ✓ Avoid heavy exercise on the day that you are collecting these samples.
- ✓ Do not collect samples within 24 hours after having dental work.

Instructions for collection:

- 2. Remove a single straw from the plastic bag. Place one end of the straw into the small container.
- 3. Place your mouth on the other end of the straw. Imagine eating your favorite food and allow saliva to pool in your mouth. (It is okay to gently chew on the end of the straw.)
- 4. Tilt your head forward and drool down the straw to collect your saliva in the small container. Do not spit or blow through the straw as this will cause excess foam. The small container should be half full of liquid not including any foam that may have formed.
- 5. Tightly screw the cap on the small container, place the small container in the re-sealable plastic bag that contains an absorbent pad, seal the bag, and place the bag in the freezer.
- 6. Complete the Saliva Data Collection Form including the time the sample was collected.

- 7. Before you go to bed, collect the second sample marked with a as described in steps 2-6. Remember you should collect this sample before you brush your teeth and at least 1 hour after eating. Complete the Saliva Data Collection Form.
- 8. Please keep the re-sealable plastic bag containing the saliva samples in the freezer until the samples can be picked up by study staff.

THANK YOU FOR YOUR HELP!

SALIVA DATA COLLECTION FORM

On what date did you collect the saliva samples? _ / / 20_			
	d d v v v	m m	
	, , , ,	,	
Container	When to Take Sample	Time Collected	
☼	As soon as you wake up	: □ am □ pm	
Please answer the following question after you have collected the 🌣 saliva sample:			
 Did you spend any time dozing in bed before you collected 			
the first saliva sample (🌣 saliva sample) this morning? 🔲 Yes 📙 No			
2. If yes, estimate of time spent dozing before collecting the ☆ saliva sample _ _ minutes			
Container	When to Take Sample	Time Collected	
*).	At Bedtime before brushing your teeth and at least 1 hour after eating for the	_ _ : _ □ am □ pm	

Please complete questions on the back.

3. During the 2 hours prior to collecting the $\stackrel{ extstyle }{\smile}$ saliva sample, have you done any of the $\stackrel{ extstyle }{\smile}$ following:
Consumed a caffeinated beverage (coffee, tea, soda)? Yes No
Smoked? DYes No
Consumed alcohol?
4. During the 2 hours prior to collecting the saliva sample, what was your level of physical activity?
None
Light (standing, light walking, light house work)
Moderate (yard work, brisk walking)
Intense (jogging, exercise classes)
counter medications today please mark None.
Please call the Study Center number on your Local Contact Sheet if you have any questions.
Thank you for taking the time to provide this information today.

For D	Data Collector's Use		
Date kit provided to participant _	/ _		
Data Collector ID :	_		
Date samples picked up	_ _ / / 20_		
Were the saliva samples frozen when received from the participant?			