

Telephone Screening Script

AFTER DETERMINING THAT CALLER IS NOT QUALIFIED FOR NCS VANGUARD STUDY:

Though you are not qualified to participate in the study, you may be qualified to participate in a different maternal and child health study titled “Evaluating the potential of saliva as a research specimen for use in the National Children's Study”. Would you like to answer a few questions to see if you qualify?

IF NO, THANK THEM AND POLITELY END THE CONVERSATION.

IF YES, CONTINUE:

The project is a component of a much larger project that will focus on maternal and child health. The project is focused on learning more about the types of measurements that can be made using saliva, with the idea that if we can learn enough from saliva that the mothers and children in the larger project may not have to give blood samples as often. That would increase the chances that mothers and children will participate in that project. The study director is Dr. Douglas A. Granger of the JHU Schools of Medicine, Nursing, and Public Health.

We will be collecting information about you during this phone call. Your taking part in this phone call is completely voluntary.

Your information will only be seen by researchers at Johns Hopkins. We will make sure that the information we collect from you is kept private and used only for the research study we are discussing. If you do not agree to continue the phone call, it will not affect your care at Johns Hopkins, nor will your private health information be kept if you are not enrolled in the study.

May I ask you a few questions to see if you are qualified for this study?

IF NO, THEN THANK THEM FOR THEIR TIME AND END THE CONVERSATION POLITELY. IF YES, THEN CONTINUE WITH THE FOLLOWING:

To be included in the study, you need to be between the ages of 18 and 35 years old, with a child between 3 months and 3 years of age. Are both of these conditions true?

IF NO, THEN THANK THEM FOR THEIR TIME AND END THE CONSERVATION POLITELY. IF YES, THEN CONTINUE WITH THE FOLLOWING:

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing 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 currently 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 (0925-0647*). Do not return the completed form to this address.

I'd like to give you some additional details. Your involvement would require for an interviewer to visit your home to administer a brief demographics questionnaire, then demonstrate how saliva collections are to be done by you to collect saliva from yourself and your child. It would also require you to then collect saliva from yourself and your child on your own, mail the saliva samples, and respond to a follow-up telephone questionnaire.

Day 1: On the day of the home visit, you will be given a consent form to read and sign, a demographics questionnaire, and then instructed in saliva collection methods for yourself and your baby. We will ask you and your child to each donate one sample on the day of the interview, but this sample is for demonstration purposes only and will be discarded. Saliva collection supplies will be left with you so that on the next day you can collect 4 additional samples at home, from yourself and your child.

Day 2: You will collect 4 samples of saliva from yourself and your baby at specific times. After all the samples are collected, we will ask you to freeze them in a container in your freezer.

Day 3: The next morning we will ask you prepare the samples for pick up or drop them off at the local FedEx or UPS.

Day 4: We will call you to ask about your experience and your ideas about how the process can be improved.

Saliva will be collected by asking you to either drool through a straw into a tube or by placing a swab under your tongue. Saliva will be collected from your child by placing an infant sized swab under the tongue.

Participants who complete the study entirely will be provided with \$25.00 by mail. Participants who do not provide samples, but complete the follow-up interview will be provided with \$15.00 by mail.

There is no cost associated with participating in this study. Your samples will be de-identified; therefore data from the samples will not be available to you. Please note that if researchers witness any abuse, neglect, or criminal activity, it must be reported to local authorities.

Do you have any questions? IF YES, ADDRESS QUESTIONS, IF NO, CONTINUE WITH:

Do you think you would like to take part in this research? If no, thank them for their time and end the call politely.

IF YES, SCHEDULE A HOME VISIT. PROVIDE CONTACT INFORMATION FOR FURTHER INFORMATION ABOUT THE STUDY: ANJALI SIVAN, 443-287-4581. THANK THEM AND POLITELY END THE CONVERSATION.