Thirdhand Smoke Contamination in a Neonatal Intensive Care Unit (NICU)

NCT04155697

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VERBAL SCRIPT (CONSENT FORM) TO TAKE PART IN RESEARCH
Thirdhand Smoke Contamination in a Neonatal Intensive Care Unit (NICU)
HSC-MS-15-0614

You are invited to take part in a research project called, *Thirdhand Smoke Contamination in a Neonatal Intensive Care Unit (NICU)*, conducted by Thomas F. Northrup, Ph.D., of the University of Texas Health Science Center. For this research project, he will be called the Principal Investigator or PI. Your decision to take part is voluntary. You may refuse to take part or choose to stop from taking part, at any time and may refuse to answer any questions.

For non-staff visitors: A decision not to take part or to stop being a part of the research project will not change the services available to you from Children's Memorial Hermann Hospital.

For medical staff only: A decision not to take part or to stop being a part of the research project will not affect your employment adversely at Children's Memorial Hermann Hospital.

The purpose of this research study is to evaluate how much nicotine is brought to the NICU on the hands of visitors and medical staff. If you agree and are able to take part in this study you will undergo the following procedures:

A cotton round will be doused with water and a powder form of vitamin C, which will be used to wipe your index (and possibly your thumb and middle) finger(s) to take a sample of the nicotine on your skin, if you are selected to complete it. You will be asked to exhale for 10 seconds into a device that measures carbon monoxide levels. This helps assess your exposure to carbon monoxide, which is commonly found in cigarette smoke. You will be asked questions about your household, basic information about yourself (age, education), and some questions about cigarette smoking and cigarette smoke exposure.

For non-staff visitors only*: If eligible and interested:* you will be asked to participate in a separate sub-study. For this sub-study you will be randomized to handwashing with soap or hand sanitization for 30 seconds (under staff instruction and observation). Then the finger swab for nicotine will be repeated twice – once immediately after your hands dry and again after an hour waiting period, during which we ask you to please avoid smoking.

Time of Participation: The total amount of time you will take part in this research study is 10-15 minutes, including the time spent reviewing this informed consent. *If eligible:* If you participate in the hand washing/sanitization sub-study, total participation will be extended by 3-5 minutes (but not including the 1-hour waiting period).

You may refuse to answer any question and may withdraw from the study, or stop any procedure, at any time. There are no known physical risks associated with adult carbon monoxide breath samples or finger-nicotine collection. Taking part in this study will not cost you anything except the time you spend completing study procedures. For non-staff visitors only*:* You will be compensated for your time. The minimum total compensation received by participating in this study is $10 and the maximum is $30, if you are eligible and take part in all study phases (including the hand washing/sanitization sub-study).

You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law.

Certificate of Confidentiality Statement

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS), National Institutes of Health. This certificate will cover all of the data collected in this study. This certificate protects the identities of research participants from any person not connected with the research itself. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you (or if applicable: "you or your child"), except to prevent serious harm to you or others, and as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself (and if applicable: "your child"), or your involvement in this research. If an insurer, employer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

The only exception to the confidentiality of the information you provide concerns the sexual or physical abuse of a child or elder, or threatened harm to yourself or others. If information on current child/elder abuse is given to the researchers, or if there are threats to harm yourself or others, the researchers are required to report this to the authorities. Except for these requirements, the Certificate of Confidentiality means that the information provided by you cannot be used in any criminal or legal proceedings.

LETTER OF INFORMATION FOR RESEARCH

Thirdhand Smoke Contamination in a Neonatal Intensive Care Unit (NICU)

HSC-MS-15-0614

You are invited to take part in a research project called, *Thirdhand Smoke Contamination in a Neonatal Intensive Care Unit (NICU)*, conducted by Thomas F. Northrup, Ph.D., of the University of Texas Health Science Center. For this research project, he will be called the Principal Investigator or PI.

The purpose of this research study is to evaluate how much nicotine is brought to the NICU on the hands of visitors and medical staff. This information may help develop policies to keep all NICU visitors, staff, and patients better protected from nicotine contamination. You have been invited to join this local research study because you are visiting a child being cared for in the NICU or you are a NICU medical staff member caring for infants in the NICU.

You can refuse to answer any questions asked or written on any forms. Participation in this study is voluntary. A decision not to take part or to stop being a part of the research project will not change the services available to you from Children's Memorial Hermann Hospital. *For medical staff only:* A decision not to take part or to stop being a part of the research project will not affect your employment adversely at Children's Memorial Hermann Hospital.

This work is being supported by a grant from the Eunice Kennedy Shriver National Institute of Child Health & Human Development. If you agree and are able to take part in this study you will undergo the following procedures:

1) A cotton round will be doused with water and a powder form of vitamin C, which will be used to wipe your index (and/or possibly your thumb and middle) finger(s) to take a sample of the nicotine on your skin. This procedure takes about 1-2 minutes to complete, if you are selected to complete it.
2) You will be asked to exhale for 10 seconds into a device that measures carbon monoxide levels. This helps assess your exposure to carbon monoxide, which is commonly found in cigarette smoke. This procedure takes about 1 minute to complete, if you are selected to complete it.
3) You will be asked questions about your household, basic information about yourself (age, education), and some questions about cigarette smoking and cigarette smoke exposure. The questions will take about 5 minutes to complete.
4) For non-staff visitors only: *If eligible and interested:* you will be asked to participate in a separate sub-study. For this sub-study you will be randomized to handwashing with soap, or hand sanitization for 30 seconds (under staff instruction and observation). After you complete the hand washing or hand sanitization you will be asked to dry your hands with paper towels and then allow them to air dry for a few minutes. After your hands air dry, you will have your thumb or index/middle finger wiped with a cotton round (and water/vitamin C solution) to sample the nicotine this finger after hand washing/sanitization. You will be instructed not to smoke for one hour and a third measurement will be taken from your thumb or index/middle finger. One to three measurements of your thumb, index, and middle finger's diameter and one measurement of your thumb, index, and middle finger's length will also be taken (to help us standardize measurements).

It will take about 10-15 minutes to complete this study. If you participate in the hand washing/sanitization sub-study, total participation will be extended by 5-10 minutes (not including the 1-hour waiting period). You will not receive any benefit from taking part in this study. This study may lead to further work on new ways to help parents and NICU staff protect babies from the effects of lingering cigarette smoke and nicotine.

There are minimal risks associated with this research. It is possible that you may feel uneasy or uncomfortable speaking about your family's smoking practices. You may refuse to answer any question and may withdraw from the study, or stop any procedure, at any time. There are no known physical risks associated with adult carbon monoxide breath samples or finger-nicotine collection.

Your decision to take part is voluntary. You may decide to stop taking part in the study at any time. If you decide to withdraw, please tell the research staff.

Taking part in this study will not cost you anything except the time you spend completing study procedures. For non-staff visitors only*:* You will be compensated for your time. The minimum total compensation received by participating in this study is $10 and the maximum is $30, if you are eligible and take part in the hand washing/sanitization sub-study and a separate study phase (which staff may discuss with you, if you are eligible).

You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law.

If you have questions at any time about this research study, please feel free to contact Dr. Northrup at (713) 500-7590, as he will be glad to answer your questions.

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To help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS), National Institutes of Health. This certificate will cover all of the data collected in this study. This certificate protects the identities of research participants from any person not connected with the research itself. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you (or if applicable: "you or your child"), except to prevent serious harm to you or others, and as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself (and if applicable: "your child"), or your involvement in this research. If an insurer, employer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

The only exception to the confidentiality of the information you provide concerns the sexual or physical abuse of a child or elder, or threatened harm to yourself or others. If information on current child/elder abuse is given to the researchers, or if there are threats to harm yourself or others, the researchers are required to report this to the authorities. Except for these requirements, the Certificate of Confidentiality means that the information provided by you cannot be used in any criminal or legal proceedings.

CPHS STATEMENT: This study (HSC-MS-15-0614) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.