STUDY TITLE: AN INTERVENTION TO REDUCE SECOND HAND SMOKE EXPOSURE AMONG PEDIATRIC EMERGENCY PATIENTS

STUDY NUMBER: R01HD083354

FUNDING ORGANIZATION: National Institutes of Health/National Cancer Institute

Melinda Mahabee-Gittens, MD
Name of Principal Investigator

513-636-7966
Telephone Number

(513) 636-4200
24 hr Emergency Contact

INTRODUCTION

We are asking you and your child to be in a research study so that we can learn new information that may help others. If you and your child decide not to be in this study, we will still take good care of you and your child. If you and your child decide to be in this study, you and your child may change your mind at any time during the study and you and your child can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you and your child decide to be in the study. You and your child can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about whether counseling parents of children who come to the Emergency Department about quitting smoking will help them quit.

We are asking you and your child and other people who smoke and their children to be in the research because it may help us understand more about the process of quitting smoking. You do not have to quit smoking or want to quit smoking in order to be a part of this study.

WHO IS IN CHARGE OF THE RESEARCH?

Dr. Melinda Mahabee-Gittens is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study.

CCHMC is being paid by National Institutes of Health/Eunice Kennedy Shriver National Institute of Child Health and Human Development to conduct this study.

WHO SHOULD NOT BE IN THE STUDY?

You cannot be in this study if you have any of the following: You are already enrolled in a smoking cessation program or are on nicotine replacement or other pharmacologic smoking cessation treatment; you are a tobacco chewer only; you are unable to speak and read English; you have no working telephone number; you are not willing to provide follow-up; you have no permanent mailing address; you have plans to move within 6 months after enrollment; you live approximately 50 miles away from the hospital or farther; you have been previously enrolled in the study. Your child cannot be in this study if he or she smokes tobacco or marijuana or has a tracheostomy.

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain each visit to you and your child. You and your child will be able to ask questions to make sure that you understand what will happen.

These are the things that may happen to you and your child while you are in the study:

- Tobacco Use Questions (you)
- Saliva, Urine, and Hand Wipes Samples (child): these samples may be analyzed to help us understand smoke exposure. We may provide urine collection kits to you at any of the visits for the study or mail them to you prior to or after the visit such that you can collect the urine sample prior to or after the visit.
- Cheek swabs from you and your child at the six week and six month home visits.
- Dust sample, surface wipe samples, and home surface area measurements (home)
- Child's Medical History Questions (you)
- Feelings About Your Child's Health (you)
- Group Assignment (Randomization): you and your child will be but into a study group by chance, like flipping a coin. You will have an equal chance of being in either study group.
    1. **Smoking Cessation Group**- Participants in this group may receive:
        - **Counseling** on quitting smoking, be connected with resources to quit smoking and may be given 6 weeks of Nicotine Replacement Therapy (such as patches or lozenges)
        - **Written Materials** and weekly communication about quitting smoking for approximately 3 months.
        - **Phone call (s)** around a month or so after your ED visit so we can ask you some questions and schedule a home visit with you and your child.
        - **6-week Follow-Up Questionnaire and Home Visit** where we may ask you questions and take samples from your child and home (mentioned above). Since this visit includes the collection of dust from your home, we may take the vacuum bag from your vacuum cleaner. You may also receive an additional 6 weeks of Nicotine Replacement Therapy.
        - **6-month Follow Up Questionnaire and/or Home Visit** where we may ask you questions and may take samples from your child and home (mentioned above)

    2. **Healthy Habits Group-** Participants in this group may receive:
        - **Counseling** on eating healthy and being active
        - **Optional viewing of websites** that have ideas on how to stay healthy
        - **Small gift** to encourage healthy behaviors
        - **Written materials** and weekly communication about how to stay healthy for approximately 3 months
        - **Phone call (s)** around a month or so after your ED visit so we can ask you some questions and schedule a home visit with you and your child
        - **6-week Follow-up Questionnaire and Home Visit** where we may ask you questions and take samples from your child and home (mentioned above). Since this visit includes the collection of dust from your home, we may take the vacuum bag from your vacuum cleaner.
        - **Optional resources** for quitting smoking and/or materials on quitting smoking
        - **6-month Follow-Up Questionnaire and/or Home Visit** where we may ask you questions and may take samples from your child and home (mentioned above)

Optional Marijuana Questions and Sample Analyses

As part of this study, we are also asking for your permission to answer a few questions regarding your marijuana use as well as for your permission to potentially have your child's samples analyzed for marijuana smoke exposure. This is an optional part of this study, and if you decide you do not want to consent for this you will still be allowed to participate in the study. Should you indicate that you smoke marijuana, we may provide you with resources to help you quit marijuana use. Please initial below to indicate whether you would like to participate in this part of the study:

_____ I consent to answer questions about my marijuana use and potentially have my child's samples

analyzed for marijuana smoke exposure.

_____ I do not consent to answer questions about my marijuana use and potentially have my child's samples analyzed for marijuana smoke exposure.

If we are unable to reach you for the follow-ups, we may also stop by your home or some other convenient location so you and your child have the opportunity to complete the follow-ups. Although it is important for the in-person visits to be done at your home, we may be able to meet you at a different place if you prefer. In addition, we may call you to schedule an extra home visit during the study period if we have additional information we need to collect from you. We may attempt to reach you by phone, email, text message, mail, or social media during the study period.

Samples collected for the study may be stored and analyzed in the future, even after the study is completed. If you consented, analyses may include tests of marijuana smoke exposure. Results from the samples will not be shared with study participants because a lot is still unknown about marijuana smoke exposure. Should bloodwork be ordered for clinical care today, we may store and analyze any unused portions of your child's blood.

If you tell us you have quit smoking completely at any point in the study, we may set up an additional home visit to ask you some questions and complete a carbon monoxide test and/or saliva sample to determine if all of the cigarette smoke is out of your system. We may also collect another saliva, urine, and/or hand wipe from your child and dust and surface wipe from your home. Participants in both study groups may have their counseling session audio recorded. The recordings are for quality improvement purposes for the study. If you or your child do not agree to be audio recorded, you will still be allowed to participate in the study.

Pregnancy: Pregnant smokers, nursing mothers, or women attempting to become pregnant during the course of this study will be allowed to participate in the study, but will not receive nicotine patches or lozenges. We may review your child's electronic medical chart for clinical information on the current visit, past visits and information on future visits.

Because this is a long-term study it is important for us to remain in contact with you for the duration of the study. Therefore, we may ask you to provide some information that will help us find you in case you move or change your phone number (e.g. your demographic information, social security number and/or the names of people who might know where you have moved). Please know that this information will not be shared with anyone without your authorization and will only be used to allow us to re-contact you in case we lose contact with you during the course of the research.

You and your child may be contacted to take part in future studies. However, new consent forms would be issued at that time (if required by our Institutional Review Board) and you will have the option to choose whether or not you would like to participate.

It is possible that at the end of the study, samples of your child's urine, blood, saliva, cheek swabs, hand wipes, and dust samples from your home may be left over. Unused portions of these samples will be stored and may be analyzed for future research. The DNA collected from your samples/cultures may be used for future research but at the current time, the exact testing to be done on DNA is not known. Samples may be shared with investigators at CCHMC as well as other institutions. Additionally, there is no scheduled date on which the samples/cultures and information in the bank will be destroyed. The samples may be stored for research until they are "used up." If you do not agree to having your child's leftover samples/cultures stored for future research, you may still participate in the study.

In some research using these samples, researchers may develop medical tests or treatments that have commercial value. You will not receive any money that may result from any such commercial tests. Also, the

results obtained from studies performed in the future on stored specimens will not be shared with you.

If you agree for your child's samples to be stored for future research, all additional research studies beyond the current study that use your child's identified samples will be reviewed by the investigator's Institutional Review Board (IRB), a special committee that oversees medical research studies to protect the rights and welfare of the human subject volunteers.

LEVEL OF IDENTIFICATION

If you agree to having your child's samples/cultures stored for future research, your child's samples/cultures will be coded so that your child's name cannot be readily identified. Reports about research done with your child's samples/samples will not be put into their health/medical record and will be kept confidential to the best of our ability within state and federal law.

In the future, researchers studying your child's samples/cultures may need to know more about you or your child, such as your age, gender, and race. If this information is already available because of their participation in the study, it may be provided to the researcher. Your name or your child's name, or anything that might identify you personally, will NOT be provided. You may be re-contacted to obtain additional information. Your child's stored specimens may be tested in the future, and may be shared with other researchers doing research.

I hereby consent for my unused samples/cultures which will not have personal identifiers to be used in future research for the purposes described above.

_____ (initials) YES, you may store my samples/cultures without personal identifiers and analyze them in future studies.

_____ (initials) NO, my study samples/cultures will be destroyed at the end of this study.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this study may not help you right now. When we finish the study, we hope that we will know more about the process of quitting smoking. This may help other people who smoke later on.

If you quit tobacco, you may reduce your risk of contracting a variety of diseases, including lung, oral or other cancers, chronic lung disease, heart disease, and gum disease.

Even if you do not make a quit attempt, you may be given information on how to go about quitting that could be useful to you in the future.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

The primary risk is the loss of privacy. The risk of such an event is very small, as every effort will be made to protect your and your child's information.

If you and your child participate in this study, you may spend an additional 30-40 minutes longer in the emergency department in order to complete the study.

You might feel uncomfortable in being asked to make an attempt to quit using tobacco.

Your child might feel uncomfortable when providing a saliva sample, but they should not feel any pain.

If you quit using tobacco, you might experience some of the common withdrawal symptoms from nicotine, such

as hunger, anxiety, restlessness, or problems sleeping.

The use of nicotine patches or nicotine lozenges, a standard treatment for tobacco cessation, is not required, but is made available for you. If you choose to use nicotine patches or lozenges, you may experience side effects during the first few days as your body adjusts to the medication, such as:

Likely, but not serious: notify your physician and the study doctor, Dr. Mahabee-Gittens (513-636-4986), if any of these symptoms occur for more than several days or become worse over time.

- Mouth pain, sores or swelling
- Headache
- Dizziness
- Lightheadedness
- Drowsiness
- Stomach upset
- Nausea
- Flushing
- Nervousness or anxiety
- Red, itchy or irritated skin where the patch is placed

Rare but serious: contact your physician and the study doctor immediately if you experience these or any other symptoms not listed; Dr. Mahabee-Gittens can be reached after hours at 513-636-4200.

- Breathing difficulties
- Chest pain
- Irregular heartbeat
- Tremors

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you and your child can choose not to be in it.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you and your child remains private is important to us. To protect your and your child's privacy in this research study we will take the following steps: All study participants will be given a unique study number which includes no personal identifying information, study forms will be kept in a locked cabinet, all computer data forms will be password protected. A copy of this consent form will be included in your child's medical research record.

By signing this consent form you and your child are giving permission for representatives of the Cincinnati Children's Hospital Medical Center ("CCHMC"), the Investigator and CCHMC employees involved with the research study including the Institutional Review Board and the Office for Research Compliance, to be allowed to inspect sections of your and your child's medical and research records related to this study.

In unusual cases, the investigators may be required to release personal identifiable information (which may include you and your child's personal identifiable medical information) related to you and your child's participation in this research study in response to an order from a court of law. If the investigators learn that you/your child or someone with whom you/your child are involved is in serious danger or potential harm, they will need to inform, as required by Ohio law, the appropriate agencies. There is a legal obligation for investigators to report child maltreatment or child abuse to the appropriate

agency.

Because nicotine is an FDA approved drug, the FDA may inspect your and your child's research records upon audit.

The information from the research study may be published; however, you and your child's personal identifying information will not be reported in such publication. The publication will not contain information about you and your child that would enable someone to determine your or your child's identity as a research participant without your authorization.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you or your child. At most, the website will include a summary of the study results. You and your child can search this website at any time.

Because this research study involves payment for participation we are required by federal Internal Revenue Service (IRS) rules to collect and use your social security or tax ID number (SSN) in order to track the amount of money that we pay you. Unless you have given specific permission for another use of your SSN related to this research we will only use your SSN to keep track of how much money we pay you and your SSN will not be used as part of this research.

WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?

The study doctor will tell you if they find out about new information from this or other studies that may affect your or your child's health, safety or willingness to stay in this study.

WILL IT COST YOU ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?

You/your insurance company will have to pay for the usual costs of your child's medical care, but you/your insurance company will not be charged any extra for participation in the study.

As part of the study, you may receive weekly email/mail/text messages about the benefit of quitting smoking or about healthy lifestyle behaviors for approximately 3 months. Depending on your cellular phone service, this could result in charges to your cellular phone bill.

Please indicate here whether or not you choose to use texting for this study.

_____ I consent to receiving and sending text messages for the study purposes. I understand that I may be charged for this on my cellular telephone bill.
_____ I refuse to receive and send text messages for the study purposes.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

You will be reimbursed for your time and effort while you are in this research study.

Reimbursement for participating will be paid on the following schedule:

$20 for completing initial baseline assessment; additional $10 if urine sample is provided
$20 for completing the 6-week follow-up questionnaire
$30 for completing the 6-week follow-up visit; additional $10 if urine sample is provided
$30 for completing the 6-month follow-up questionnaire
$35 for completing the 6-month follow-up visit, if based on your responses to the survey at 6 months, you are selected for a home/other visit; additional $10 if urine sample is provided

$10 bonus if you complete both the 6-week and the 6-month follow-up. In order to receive this completion bonus you must complete the 6 week questionnaire, 6 week home visit, 6 month questionnaire, and 6 month home visit (if applicable).

We will give you your payment in the form of a reloadable debit card (ClinCard) and you will receive a handout that will explain how to use the card. We will provide you with a card and we will load money onto your card after each visit that you complete based on the schedule listed above. Incentives will be mailed and/or provided in person during a visit to CHMC or at your home. A W-9 form may need to be completed by you in order to receive the incentive.

WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?

If you believe that you or your child have been injured as a result of this research you should contact Dr. Melinda Mahabee-Gittens at 513-636-7966 as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If you or your child go to the Emergency Room or to another hospital or doctor it is important that you tell them that you and your child are in a research study. If possible, you should give them a copy of this consent form.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your/your child's "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

CCHMC will need to use and share your/your child's PHI as part of this study. This PHI will come from:
- Your child's CCHMC medical records
- Your/your child's research records

The types of information that will be used and shared from these records include:
- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your or your child's protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you/your child as part of this study
- Other individuals and organizations that need to use your/your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the

study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your or your child's PHI is not misused?

People that receive your/your child's PHI as part of the research are generally limited in how they can use your/your child's PHI. In addition, most people who receive your/your child's PHI are also required by federal privacy laws to protect your/your child's PHI. However, some people that may receive your/your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you/your child change your mind?

You and your child may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your/your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you or your child will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your/your child's other medical care be impacted?

By signing this document you agree to participate in this research study and give permission to CCHMC to use and share your/your child's PHI for the purpose of this research study. If you refuse to sign this document you and your child will not be able to participate in the study. However, your/your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

WHAT ELSE SHOULD YOU KNOW ABOUT THE RESEARCH?

Making sure that information about you and your child remains private is important to us. To protect your and your child's privacy in this research study we will maintain all of your and your child's records from this study (research records) separately from your child's medical records.

If you decide to take part in the part of this research study that collects information on marijuana and potentially analyzes your child's samples for marijuana smoke exposure, you will be asked to give us information about marijuana use. A Certificate of Confidentiality has been obtained from the Federal Government for this study to help protect your privacy. This Certificate means that the researchers cannot be forced to give out research information that tells who you are, even by court subpoena, in any federal, state, or local, civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to refuse to release research information about you in legal matters that would identify you or your child:

This includes any legal matters that are:
- Civil
- Criminal

- Administrative
- Legislative
- Other proceedings

The Certificate of Confidentiality does not prevent the researchers from voluntarily disclosing information that would identify you under the following circumstances: 1) if we see (learn) something that would immediately endanger you, your child, or others, 2) if the we learn about your/your child's intent to do serious harm to yourself or others, 3) if we suspect or see child abuse and/or neglect. In such cases, we would only disclose information to the extent necessary to prevent harm to the person(s) believed to be endangered.

You should also understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself, your child, or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive such information, then the researchers may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of **Child** Research Participant

_____
Printed Name of **Adult** Research Participant

_____ _____
Signature of Legally Authorized Representative* indicating Parental Permission and Adult Consent to Participate — Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be

provided

Signature of **Adult** participant Date

Signature of Individual Obtaining Consent Date