DEVELOPMENT AND IMPLEMENTATION OF A TOBACCO AND ENDS USE INTERVENTION FOR ADOLESCENTS AND YOUNG ADULTS IN THE PEDIATRIC HOSPITAL

CONSENT/ASSENT TO PARTICIPATE IN A RESEARCH STUDY AT CHILDREN'S MERCY HOSPITALS

Hi. Welcome to Children's Mercy Hospitals.
We would like to discuss an option to participate in research.

What is Research?

Research is a **set of steps or the use of a systematic process to gather data and analyze information** to increase our understanding of a topic or issue.

Research consists of three steps: Ask a question, collect data to answer the question, and review the data to answer the question.

Researchers perform research to increase our knowledge about disease processes or possible cures. Research can help us learn how to do things better, make better medicines or other treatments.

WHAT IS INFORMED ASSENT/CONSENT?

Informed consent is a learning process about a research study. We go through this process so you can learn about the study and ask questions.

We are asking you to be a part of this research study.

• Please read all of the information provided.
• Ask questions about anything that you do not understand before you make a choice to be in a research study.

SUMMARY

We are asking you to be in this research study. Being in a research study is completely voluntary, and your choice will not affect your regular medical care. This study is being done to learn how we can help adolescents and young adults stop vaping and using tobacco products.

If you decide to participate, the following things are part of this study:

- Collecting information
- Optional saliva (spit) collection
- Completing surveys
- Being randomly assigned to one of two groups (described in more detail below) to discuss your vaping and tobacco use.

There is minimal risk to participating in this study and there are no direct benefits if you participate. However, your input is very important in helping us learn how to make care better. Instead of being in this study, you can continue to get regular medical care. If you do not want to participate in this study but would like to learn more about how to quit smoking or vaping you can ask your medical team for more information.

WHO IS DOING THIS STUDY?

A study team led by Dr. Masonbrink is doing this study. Other health care professionals may help them. Funding for this study comes from the National Institutes of Health. The study team will not receive any personal payment because of your decision to participate.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to learn about how the intervention you took part in might work and if it's a good idea to use it as part of how we take care of adolescent and young adult patients in the hospital.

WHO CAN BE IN THIS STUDY?

Each study has criteria for who can be involved. The study team will review these with you to see if this study is right for you.

Are you eligible? You are eligible if you are between 14-21 years old, admitted to the hospital and have vaped in the past 30 days

Up to 144 participants will be asked to be in this study at Children's Mercy Hospitals. We are asking you to be a part of this research study because you received education from a doctor about how to stop using tobacco or nicotine.

If your parent is here with you today, they will get an information sheet about the study.

WHAT WILL HAPPEN TO ME IN THIS STUDY?

Collecting Information:

- The study team will get information from your medical record. The information collected will include age, insurance type, whether you were prescribed nicotine replacement therapy and your cotinine level.
- We will ask you to take a survey on an iPad while in the hospital. They survey will ask about your experiences with substance use, including vaping and tobacco use, and will take approximately 20 minutes to complete.
- We will ask you to provide an optional saliva (spit) sample during your initial session in the hospital.
- We will ask you to take a follow up survey 3 months after your initial session in the hospital. This survey will take up to 30 minutes to complete.
    - We will send the link to this survey by email and/ or text via Twilio. We will call you to remind you about the follow up survey if you don't complete the survey after the link is sent.
    - For participants who report that they have quit any form of tobacco use a saliva sample kit will be mailed to their house with a pre-paid label for return of their sample. Participants will also have the option of completing a home saliva cotinine test which does not require return mailing. Home saliva cotinine tests will be mailed to the participant and the study team will then schedule a secure Microsoft Teams video call to witness the test completion and result or photos of test results can be emailed at a convenient time to a secure research study email address, phmteenresearch@cmh.edu.
- We will know if you complete the surveys, but we will not know how you answered the survey questions. Your name will not be linked to your answers.

If you agree to the saliva (spit) sample, this sample might be tested for certain substances, such as nicotine, and genome sequencing, which is the process of determining the genetic makeup of a person. Any information from this testing will be kept confidential and not shared with anyone outside of our research team or with your medical record.

- A human cell contains thousands of genes. Genes contain the information needed to build and operate a human body. The basic structure of genes is DNA, which stands for deoxyribonucleic acid. Everyone's genes are

different. This explains differences like eye color, hair color, and blood type. Gene differences also partly explain why some people, but not others, get certain diseases. Information about gene differences among people can help researchers discover new tools to diagnose and treat inherited diseases. DNA testing will be done on your saliva sample collected for this study.

You will be placed into one of the two groups. The groups will be:

Group 1:

- You will get brief information about how to quit vaping or smoking during your hospital stay.
- You will be given information about programs to help young people quit vaping or smoking.
- We will audio record the conversation you have with the study team during the intervention. We will use the recording to make sure we are doing the session right. These recordings will be deleted upon completion of the study or up to 5 years after recorded.

Group 2:

- Someone from the study team with spend some extra time with you to talk about substance use, vaping and tobacco use, and ways we can help you make healthy decisions.
- You may be prescribed a medication called nicotine replacement therapy or NRT to help you quit vaping or smoking.
- We will reach out to you by phone once weekly for the next 4 weeks (4 phone sessions) to talk about vaping. We will also refer you to a vaping and smoking quit program.
- We will talk to you about resources you can use to help make healthy decisions. If you would like to use these resources, a doctor or health educator may talk to you to make sure these resources are a good fit for you. You may choose not to use any of these resources. The choice is up to you.
- We will audio record the conversation you have with the study team during the intervention. We will use the recording to make sure we are doing the intervention right. These recordings will be deleted upon completion of the study or up to 5 years after recorded.
- While you are in the hospital, you will be asked to complete a survey on an iPad. This survey will ask about what you think about the intervention and your thoughts on substance use and vaping and it will take approximately 15 minutes to complete.

The group to which you will be assigned will be decided randomly, like tossing a coin. There is an equal chance of you being assigned to either group. Your doctor cannot decide which group you will be assigned to. You should take part in this study only if you agree to be in any of the study groups.

Optional Use of Information and Samples for Future Research: This study is collecting data and biospecimens from you. We would like to make your data and leftover biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data and leftover biospecimens for up to 5 years. There will be no direct benefits to you for the storage and future research use of the information and leftover biospecimens. However, sharing your data and leftover biospecimens may contribute to research that could help others in the future.

- De-identified: Your name and identifying information will be removed from any data and biospecimens you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and biospecimens.
- You can choose to be only in the main study.
- If you say no to this additional future research, the left-over biospecimens will be destroyed once all study procedures are completed. Your decision will not affect your care in any way.

- You may change that decision at any time. If you change your mind, you should contact the study coordinator, Shelbie Wooten at Children's Mercy Hospital at 816-302-3086. However, if some of the research with your leftover biospecimens has already been completed, the information from that research may still be used.
- You will be asked to mark your choice at the end of this form.

If you are less than 18 years old:
When you reach adulthood (18 years of age), during your next interaction with a study team member we will ask if you want to give consent to continue your participation in this study and/or use of your saliva samples.

If you cannot be reached or choose not to consent, the link between your identifiable information and the collected samples will be destroyed. No identifiable information will be saved. The de-identified information and samples will be kept for possible future research.

WHAT ARE THE RISKS?

Survey Risks:
The questions asked may be uncomfortable or embarrassing. These risks are minimum and unlikely to occur. You do not have to give any information you do not want to give. Your confidentiality will be protected to the greatest extent possible. You don't have to answer any questions if you don't want to. You can stop being in the study at any time. If you want to talk to a social worker today, you can let the study team or your hospital team know.

Medication Risks:
If you are prescribed nicotine replacement therapy there are certain risks associated with this medication. These include: Local skin reactions (redness, itching, burning); Sleep disturbances (abnormal dreams, insomnia); dizziness, headache, palpitations; Nausea/vomiting, Hiccups, Mouth and throat irritation, jaw muscle soreness (related to gum chewing).

Saliva Collection Risks:
There is minimal risk involved in obtaining saliva samples.

If you agree to the saliva (spit) sample, this study includes genetic analysis of the saliva sample. If your genetic information is given to someone without permission, it could impact your ability to get or keep a job, your ability to get life insurance, your immigration status, increase your risk for a lawsuit related to paternity, or impact your social reputation. These risks include the chance of discrimination.

A risk of having genetic testing is the chance for discrimination. However, a Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate based on genetic information. This law generally will protect you in the following ways:

- Health insurance companies, group health plans and employers with 15 or more employees may not request your genetic information that we get from this research, except in very limited circumstances.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility, benefits or premiums.
- Employers with 15 or more employees may not use the genetic information that we get from this research when making a decision to hire, promote, or fire you now, or in the future, or when setting compensation or the terms or privileges of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Confidentiality Risks:

- There is a slight risk of loss of confidentiality. Your confidentiality will be protected to the greatest extent possible.

There also is a risk to confidentiality when using the internet. By providing your email or phone number, the study team may communicate with you regarding setting up appointments, sending copies of consent forms and any other non-clinical, study related communication. If you are enrolled in the My Children's Mercy Portal the study team may also communicate with you via the portal. Please be aware of the following:

- Corresponding through electronic communication methods is not a secure method of sending information and others may be able to access the information sent.
- The information may not be secure if storing or viewing the consent document on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena.
- Information that is sent electronically may be kept on the Hospital's or your service provider's (Google, Yahoo, MSN, etc) network servers. Unlike paper copies, e-copies delivered directly to your PED may not be able to be permanently removed.
- Information shared through the portal may be saved as a part of your permanent medical record.

The Hospital is not liable for any security breaches of your information sent electronically.

What if I am not ok with the risk to confidentiality?

This research requires the use of your information. If you choose not to let these groups collect, use and share the information as explained above, you will not be able to participate in this research. If you choose not to allow us to use the information required, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related.

There are a few situations where confidentiality would not be kept (if you verbally tell us that you or another teen/child has been hurt or is in danger). This includes physical and sexual abuse or other abuse you may have experienced. If you choose to talk to the study team about an unsafe or abusive situation, this information will be reported to the appropriate organizations and hospital personnel.

Mandated reporting

- If you are less than 18 years old:
    - There are a few situations where confidentiality will not be kept. If you tell the study team that you or another teen or child has been hurt or is in danger, the study team will need to talk to the team taking care of you in the hospital today and someone will speak to you while you are here. If the study team has concerns that you are in a severely abusive relationship or that you might not be safe, they will need to tell your healthcare team and someone will speak to you about this today. To make sure you are safe, someone may also need to speak to your parent or guardian about it. CMH personnel, as mandatory reporters, are required to report physical or sexual abuse to the authorities.
- If you are 18 years of age or older:
    - If you verbally tell the research team about suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect, CMH personnel, as mandatory reporters, are required to report it to the authorities.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide you as evidence unless you have agreed. This protection includes federal,

state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your child's information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

If suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect are witnessed within your home, CMH personnel, as mandatory reporters, are required to report it to the authorities.

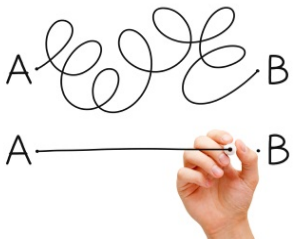
If you have any of these problems or changes in the way you feel, you should tell the investigator or other study personnel as soon as possible.

WHAT ABOUT OTHER RISKS WE DON'T KNOW ABOUT?

There may be risks we don't know about right now.

We will tell you about any new information that might change your decision to stay in the study.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?



There may be no direct benefit to you from being in this research study. By being in this study, you may help researchers find better treatments for adolescents and young adults who vape or use tobacco products in the future.

WHAT ABOUT EXTRA COSTS?

You **will not have to pay anything extra** if you are in this study.

Your research visit may be combined with a routine care visit. Your insurance company will still be required to pay for all of your routine care that would have occurred if you were not part of this research study.

WHAT WILL I RECEIVE FOR BEING IN THIS STUDY?

You may be compensated up to $60 if you complete all parts of this study. Below is the payment schedule:

Today's visit	3-month follow-up survey	3-month saliva sample mailed back or home test completed
$15	$20	$25

If the total value of payments provided to you from Children's Mercy Hospitals totals more than $600 each in any calendar year, the hospital must report this to the IRS on a Form 1099 with the recipient's social security number

(SSN) or individual tax identification number (ITIN). You will receive a copy of this tax form. Accepting payment for taking part in the study may affect eligibility for Medicaid or other programs.

If you do not complete the study, you will be compensated for the visits that were completed. You will not be compensated for any unscheduled visits.

WHAT ARE THE ALTERNATIVES TO BE BEING IN THIS STUDY?

Instead of being in this study, you may choose not to participate. If you choose not to enroll in this study, your routine care will remain unchanged.

WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

Being in a research study is voluntary. You do not have to be in this study to receive medical care. If you choose not to be in this study or withdraw from this study, there will be no penalty or loss of benefits to which you are otherwise entitled.

We will inform you of any new information that we find out during this study. This information may affect your decision to stay in the study. If you choose to withdraw from (quit) the study or if you are asked by your personal doctor to withdraw from the study, you must tell the study team as soon as possible.

If you withdraw from the study early for any reason, the information that already has been collected will be included in the study database. No further information will be collected for the study.

Dr. Masonbrink or the Institutional Review Board may stop the study at any time. The investigator(s), your doctor, or the Institutional Review Board may remove you from the study at any time without your consent.

Authorization about Use and Disclosure of Health Information for Research Purposes

This research involves the use and sharing of your health information. Your health information is **protected by a federal privacy law called Health Insurance Portability and Accountability Act (HIPAA)**. HIPAA gives you the right to decide who can collect, use, or share your protected health information. HIPAA also requires this information to be kept secure and private. This form describes how the information collected about you for this research will be used and shared with others if you choose to participate in this research.

What Information is "Protected Health Information" (PHI)?
Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. Health information is considered "protected health information" (PHI) when it may be possible to figure out who the person is. For example, when a person's health information is combined with identifiers like name, address, phone number or social security, then the information is considered PHI.

What information about me will be accessed, collected and recorded in the research record?

The following information about your health will be used for this research: Your age, your medical history and prescription medications.

The research record is separate from your medical record. Information about you that is obtained during this study will be recorded in a research record and may also be recorded in your medical record. A research record will be created

and kept in the secure CMH research office in pediatric hospital medicine. The research record may include documents that have your: name, assigned study ID number, home street address, telephone number, medical record number, hospital account number, social security or individual taxpayer identification (ITIN) number, date of birth, dates of service, email address, or voice recording. All research records will be maintained in a confidential manner.

Who will be allowed to access and record my health information in the research record?

The following people and entities will have access to your health information and/or PHI for this research:

The research team, which includes persons involved in this study at Children's Mercy Hospitals;
Dr. Masonbrink and the people or groups hired to help perform this study;
The Institutional Review Board at Children's Mercy Hospitals;
Other researchers, hospitals, and institutions that are part of this study and their Institutional Review Boards;
A group that oversees the data (study information) and safety of this research;
People from organizations that provide independent accreditation and oversight of hospitals and research;
Government/regulatory agencies (both US and international), such as the Office for Human Research Protections the Food and Drug Administration, the National Institutes of Health offices whose job it is to protect human subjects and oversee the conduct of research.

How is the information protected?

For this study we will:
Store your data in a secured way using normal business practices (like using password protected computers, limiting the number of authorized personnel who can see your identifiers, using a code number instead of your name, or removing your identifiers when possible to do so);
Share your health information only when we must;
Share only the information that is needed to satisfy the request;
Request anyone who receives the collected health information from us to protect your privacy; and
Not use your name in any publication or presentation of the research results. You will be told of your study results when they are made public. Thus, you need to tell your doctor or clinic coordinator when your contact information changes.

Absolute confidentiality cannot be guaranteed because persons outside the research team may need to look at the research records that include your identifying information. Once your information is shared, we cannot promise that it will remain private. Some people or groups who get your identifiable health information might not have to follow the same privacy rules that we follow. They may pass information on to other groups or individuals not named here. If that happens, your information will no longer be protected by the HIPAA privacy laws.

What if I'm not ok with using my PHI?

Because we need your permission to use your health information, you cannot participate in this study unless you sign this form. If you choose not to allow us to use your protected health information, we will discuss any non-research alternatives available to you.

Refusing to sign won't affect your access to other medical care, your payments, eligibility for benefits, or ability to enroll in any health plans.

What happens if I change my mind later?

You may withdraw your permission for us to use your PHI for this research study by sending a written notice to Dr. Masonbrink at 2401 Gillham Road, Kansas City, Missouri 64108. You may also contact Children's Mercy Hospitals Health Information Management (HIM) in writing. **If you cancel your permission to use and share your information, you may no longer participate in this research.**

We may still use and share information that was collected before receiving your cancellation. If we have sent your health information to a third party, such as the research sponsor, or we have removed your identifying information, it may not be possible to prevent its future use.

If you do not cancel your permission, your PHI may continue to be recorded until the entire study is finished. This may take years. Your permission to use and share your health information will not expire unless you cancel it.

Can I ask to see the PHI that is collected about me for this research?

The federal HIPAA rules state you have the right to access your medical records. A copy of this research consent/HIPAA authorization form may be placed in your medical record. Additionally, information about medications, tests and other procedures conducted as part of the research study may also be placed in your medical record if relevant to your clinical care, and may be viewed by individuals with access to your medical record (e.g. other health care providers).

Any research information that is placed in your medical record will be kept there indefinitely.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Dr. Masonbrink is in charge of this research study. You may call Dr. Masonbrink at 816-802-3236 with questions at any time during the study. You may also call Shelbie Wooten the study coordinator, at 816-302-3086 with any questions you may have.

You should call Dr. Masonbrink if you believe that you have suffered injury of any kind as a result of being in this research project.

You may also call the Children's Mercy Hospitals' Pediatric Institutional Review Board (IRB) at (816) 731-7474 with questions or complaints about this study. The IRB is a committee of physicians, statisticians, researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

E-CONSENT/ASSENT OF SUBJECT

The purposes, procedures, and risks of this research study have been explained to me. I have had a chance to read this form and ask questions about the study. Any questions I had have been answered to my satisfaction. I consent to be in this research study. A copy of this signed eConsent form will be given to me.

Your signature means you agree to the following statements:
I have had a chance to discuss the study and ask questions. My questions have been answered.
I understand the purpose, the required procedures, risks and benefits involved if I participate in the research.
I understand that I do not have to be in this study.
I know I can decide to quit the study at any time.
I agree to be in the study.

Making Your Choice for Optional Future Research

Please read each sentence below and think carefully about your choice. After reading each sentence, circle "Yes" or "No" and initial each item.
I agree that my saliva samples and clinical information can be used by other researchers in the future to study differences in nicotine metabolism.

Yes No _____ Initials

Signature of Adult/Adolescent	Date	Relationship to Participant

Print name of Adult/Adolescent

STUDY PERSONNEL

Your signature means you have confirmed that legally effective consent has been obtained.
I have explained the purposes, procedures, and risks involved in this study in detail to the participant.
I have answered all questions.
I attest that, in my judgement, the participant possesses the legal capacity to give informed consent freely.
I have confirmed the agreement of the participant and obtained their signature documenting that agreement.

Signature of Person Obtaining Consent/Assent	Date	Time

Print Name of Person Obtaining Consent/Assent _____