

## CONSENT FORM TO BE PART OF A RESEARCH STUDY

**Title of Research:** Evaluating the Effectiveness and Long-Term Impact of a Tobacco & Nicotine Education Program

**UAB IRB Protocol #:** IRB-300004652

**Principal Investigator:** William H. Coleman, MD

**Sponsor:** Office for Family Health Education & Research, UAB School of Medicine

<b>General Information</b>	Your child is being asked to take part in a research study. This research study is voluntary, meaning your child does not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
<b>Purpose</b>	The purpose of the study is to find out if students will smoke or vape after having tobacco and nicotine education during grades 5 – 12.
<b>Duration &amp; Visits</b>	Your child will be in this study for up to 7 years, if they are in 5 <sup>th</sup> – 12 <sup>th</sup> grades in this school system from 2019-20 to 2025-26.
<b>Overview of Procedures</b>	You child will be asked to complete a survey with questions about what they know about tobacco and nicotine and whether they have tried smoking or vaping.
<b>Risks</b>	The only risk is related to the potential loss of confidentiality.
<b>Benefits</b>	Your child may benefit by improved tobacco and nicotine education efforts.
<b>Alternatives</b>	The alternative is that your child not participate in this study.

### **Purpose of the Research Study**

We are asking your child to take part in a research study. The purpose of this research study is to find out if giving tobacco and nicotine education lessons every year from grades 5 – 12 will keep students from smoking or vaping. All 5<sup>th</sup> – 12<sup>th</sup> grade students in the Fort Payne City School System and the Scottsboro City School System will be asked to take a voluntary survey. Up to 4,000 students per year could take the survey.

### **Study Participation & Procedures**

If you agree for your child to join the study, once a school year the homeroom or first period teacher will direct students to the survey on their school-issued electronic device (laptop or tablet). It should take about 15 minutes to complete the survey. The survey does not ask for the student's name. Results will automatically load into a spreadsheet that will be viewed only by the researchers. Annual summary reports of the survey results will be shared with the school system superintendents. At the end of the 7-year project, a report will be prepared for publication in a journal.

The survey is voluntary and students can skip some or all of the questions. The teachers and researchers will not know which students do or do not complete the survey.

### **Risks and Discomforts**

As with any research, there is always a small risk of loss of confidentiality. While the survey asks sensitive questions about tobacco and nicotine use behavior, several steps are taken to protect your child's confidentiality. The student can skip any or all questions; neither your child's nor their teacher's name will appear with the results; and only the researches will see the survey results. If you deny your child participating in the survey, their school-issued electronic device (table or laptop) will be taken up by the teacher for the duration of the survey time. This could cause your child social discomfort as others in the class will know they

are not participating.

### **Benefits**

Your child might not benefit directly from taking part in this study. However, this study may help the school systems decide which grades to give tobacco and nicotine education.

### **Alternatives**

The alternative to participating in this research is to not take the survey. Even if your child doesn't take the survey this year, in future years they can join this research by taking the survey.

### **Confidentiality**

Information obtained about your child for this study will be kept confidential to the extent allowed by law. The survey will ask students to tell their age, gender and race, but not their name or their teacher's name. This research information may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- the Office for Human Research Protections (OHRP)
- the Office for Family Health Education & Research, UAB School of Medicine

The information from the research may be published for scientific purposes; however, an individual child's information will not be given out in those publications.

### **Voluntary Participation**

Whether or not your child takes part in this study is your choice. There will be no penalty if you decide your child will not be in it. If you decide your child will not be in the study, your child will not lose any benefits they are otherwise owed.

If you **DO NOT want your child to participate in the survey, please call the UAB Research Team at 256-551-4609**. Provide your child's name, grade, school and homeroom teacher. State that your child does not have permission to participate. Your child's teacher will be notified and the teachers will collect your child's electronic device during the time the survey is conducted (about 15 minutes). Taking part in this research is not part of your child's class work or duties. You can refuse to enroll your child, or withdraw them after enrolling at any time before the study is over, with no effect on your child's class standing or grades. Your child will not be offered or receive any special consideration they take part in this research.

### **Cost of Participation**

There is no cost to participate in this research.

### **Payment for Participation**

There is no payment for participating in this research.

### **Questions**

If you have any questions, concerns, or complaints about the research please contact the principal researcher, Dr. Bill Coleman, at 256-551-4609 or e-mail care of [paulaclawson@uabmc.edu](mailto:paulaclawson@uabmc.edu)

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.