

CONSENT  
Exempt Online

Examining the Appeal of Nicotine Pouches in Ohio Appalachia  
NCT Number: NCT05236894  
Consent Approval Date: 05/31/2022

11 **The Ohio State University Consent to Participate in Research**  
12  
13

**Study Title: Examining the Appeal of Nicotine Pouches in Ohio Appalachia**

**Protocol Number: 2021C0199**

**Researcher: Brittney Keller-Hamilton, PhD, MPH**

**Sponsor: The Ohio State University**

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15  
16 **This is a consent form for research participation.** It contains important information about  
17 this study and what to expect if you decide to participate.

18 **Your participation is voluntary.**

19 Please consider the information carefully. Feel free to ask questions before making your  
20 decision whether or not to participate. Your participation in this research study will not impact  
21 your affiliation with The Ohio State University in any capacity. You may withdraw from the  
22 study at any time.

23  
24 **Purpose:**

25 Nicotine pouches are new smokeless tobacco products that are marketed as substitutes for  
26 cigarettes and are gaining in popularity. They may make a big impact in regions of Ohio  
27 known as Appalachia and surrounding rural areas. There is little research on how nicotine  
28 pouches will be adopted by residents of Ohio Appalachia and rural Ohio. We want to better  
29 understand the appeal and potential impact of nicotine pouches on public health.

30  
31 We ask participants to provide blood samples for nicotine content analysis, which will show  
32 us how much nicotine is absorbed by your bloodstream as you use nicotine pouches or smoke.  
33 This is very helpful for us to understand how nicotine is absorbed by the body. Additionally,  
34 the questionnaires you answer will help us understand how and when you became a smoker,  
35 how much you like or dislike the nicotine pouches, and also how you feel while using nicotine  
36 pouches or cigarettes. There are two groups enrolling into this study. Participants enrolled in  
37 Aim 1 are from Ohio Appalachia and surrounding rural areas and participants enrolled into  
38 Aim 2 can be from anywhere in Ohio. You are enrolling into Aim 1, which focuses on the  
39 differences between nicotine pouches and cigarettes. Participants can only enroll in one aim  
40 and not both.

41  
42 **Procedures/Tasks:**

43 This study will enroll 40 adult cigarette smokers from Ohio Appalachia and surrounding rural  
44 areas in Ohio.  
45

46 We invite participants to visit our lab for 3 study visits. If transportation to our lab is a  
47 challenge, transportation via Lyft services may be available to you for two out of three of your  
48 study visits. You will be asked to abstain from all tobacco products for 12 hours before each  
49 visit to provide the study team with a baseline value of the nicotine levels in your blood.  
50 During each visit, you will be randomly assigned to smoke your usual brand of cigarettes or  
51 try a nicotine pouch provided by the study. You will smoke for 5 minutes or keep the nicotine  
52 pouch in your mouth for 30 minutes. During this time, research staff will ask a series of  
53 questions and perform 7 blood draws.

54  
55 During each visit, you will have an IV placed in one of your arms to make the series of blood  
56 draws less invasive. 3mL, or a little less than 1 teaspoon, of blood will be drawn at 7 intervals  
57 over the course of 90 minutes. The IV will be placed and blood draws will be performed by a  
58 trained research nurse.

59  
60 At the beginning of each visit, participants who are capable of becoming pregnant will be  
61 asked to take a urine pregnancy test. If you are found to be pregnant, you will be withdrawn  
62 from the study.

63  
64  
65 **Duration:**

66 This study involves 3 study visits. The study timeline for each participant will vary, however,  
67 each visit will take place 2 or more days after the previous visit and ideally within 2 weeks.  
68 We ask participants to complete all 3 visits within two months of enrollment.

69  
70 Each study visit is expected to take about 3 hours.

71  
72 You may leave the study at any time. If you decide to stop participating in the study, there  
73 will be no penalty to you, and you will not lose any benefits to which you are otherwise  
74 entitled. Your decision will not affect your future relationship with The Ohio State  
75 University.

76  
77 **Risks and Benefits:**

78  
79 Every attempt will be made to reduce risk to you. Nicotine pouches are no more harmful than  
80 cigarettes and may even be less harmful. Questionnaires and blood collection involve minimal  
81 risk to you. The IV placed is similar to a routine blood draw that would be performed for a  
82 clinic visit. Potential risks are as follows: risk of using nicotine pouches, use of cigarettes, loss  
83 of confidentiality or privacy, potential for interrupting your plans to quit smoking, and slight  
84 risk of discomfort, bruising and infection with blood draw.

85  
86 You are not expected to directly gain any benefits from this study. Through your contributions  
87 to science, you provide insight into a new tobacco product that has potential to impact tobacco  
88 use in Ohio Appalachia and surrounding rural areas. Moreover, data collected will inform  
89 public health efforts, policy, and clinical care in this region.

90

91 While this trial is not without risk, every effort will be taken to reduce risk and undue burden  
92 on participants.

93  
94 Participating in this study might make it harder to quit smoking. If you plan to quit smoking  
95 in the next 3 months, you should not enroll in this study. We do not want to ask smokers who  
96 want to quit to continue smoking. Please ask our PI about any questions you may have about  
97 nicotine pouches, smoking, or smoking cessation.

98  
99 Study product or cigarette use: It is important to note that nicotine pouches are no more  
100 harmful than cigarettes. If at any point you are uncomfortable with using the nicotine pouch,  
101 please notify study staff immediately.

102  
103 Slight risk of bruising, discomfort and infection with blood draw: Blood will be collected by  
104 trained research staff. Sterile instruments will be used and for blood draws, the participants  
105 skin will be cleaned with an alcohol wipe at the venipuncture site.

106  
107 Breach of confidentiality: All information linking your name to the study will be stored in our  
108 secure platform, REDCap or in a locked filing cabinet. You will be given a participant ID and  
109 all information collected will be stored under that ID. Your study information will be stored in  
110 the secure database, REDCap. Only trained members of the study team will have access to  
111 your data. Moreover, any paper documents regarding your visit will be stored in a locked  
112 filing cabinet with keys kept by the study PI and manager. Finally, your blood samples will be  
113 deidentified – meaning including your participant ID and not your name - and stored in a  
114 freezer in a locked room. While a breach of confidentiality is possible through hacking or  
115 another means of forced entry, we believe the risk is low.

116  
117 If you experience any bad reactions or issues as a result of this study, please report to our  
118 trained research nurse and study staff and, if severe, seek treatment immediately. Any  
119 treatment you seek as a result of this study will be covered by you.

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122 **Confidentiality:**

123  
124 We will work to make sure that no one sees your online responses without approval. But,  
125 because we are using the Internet, there is a chance that someone could access your online  
126 responses without permission. In some cases, this information could be used to identify you.

127  
128 Confidentiality will be maintained by numerically coding all data, disguising identifying  
129 information, and keeping data locked in file drawers or in a secure, password protected  
130 database. All biospecimen samples are kept in a locked freezer and also will be deidentified.  
131 Names of participants will be kept separate from participant data. Only study staff will have  
132 the information that connects participants' names and ID numbers. All electronic data will be  
133 numerically coded and stored in a password-protected database, on a password-protected  
134 computer in a secure research space. Participant information will be accessible only to

135 research staff, who are pledged to confidentiality and have completed training in the ethical  
136 conduct of research. Identifying information will not be reported in any publications.

137  
138 Also, there may be circumstances where this information must be released. For example,  
139 personal information regarding your participation in this study may be disclosed if required by  
140 state law. Also, your records may be reviewed by the following groups (as applicable to the  
141 research):

- 142 • Office for Human Research Protections or other federal, state, or international  
143 regulatory agencies;
- 144 • The Ohio State University Institutional Review Board or Office of Responsible  
145 Research Practices;
- 146 • Authorized Ohio State University staff not involved in the study may be aware that  
147 you are participating in a research study and have access to your information; and
- 148 • The sponsor, if any, or agency (including the Food and Drug Administration for FDA-  
149 regulated research) supporting the study.

150  
151 Your de-identified information may be used or shared with other researchers without your  
152 additional informed consent. Your deidentified blood samples may be sent to an outside lab  
153 for analysis. Your name would never be connected with the sample.

154  
155 We will not recontact you every time we use your sample or data from the questionnaires for  
156 analysis.

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158 **Future Research:**

159  
160 You will be given the option to be contacted for future, related studies.

161  
162 Your selection for being contacted about related studies will not impact your eligibility for  
163 this study.

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165  
166 **Incentives:**

167 By law, payments to participants are considered taxable income. You may receive up to \$500  
168 for your participation. After each visit, you will receive \$150 on a pre-paid ClinCard. If you  
169 complete all of your visits in a month, you will receive a \$50 bonus at the end of your third  
170 visit. If you complete baseline surveys but do not complete the blood draw portion of the visit,  
171 we will provide a \$50 pre-paid ClinCard to thank you for your time.

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173  
174 **Participant Rights:**

175 You may refuse to participate in this study without penalty or loss of benefits to which you  
176 are otherwise entitled. If you are a student or employee at Ohio State, your decision will not  
177 affect your grades or employment status.

178

179 Additionally, if at any point you decide to quit tobacco and/or nicotine products, please let us  
180 know and we will withdraw you from our study. If you wish to withdraw from the study,  
181 please contact the program manager Hayley Curran by phone or email and state your desire to  
182 withdraw from the study. Our phone number is 614-366-9693 and our lab email is BKH-  
183 Lab@osumc.edu If you withdraw, data you previously provided to the study may have  
184 already been used for analyses or publication; however, no new information will be accessed  
185 or analyzed from the time of withdrawal onward.

186

187 If you choose to participate in the study, you may discontinue participation at any time  
188 without penalty or loss of benefits. By agreeing to participate, you do not give up any  
189 personal legal rights you may have as a participant in this study.

190

191 An Institutional Review Board responsible for research involving human subjects at The Ohio  
192 State University reviewed this research project and found it to be acceptable, according to  
193 applicable state and federal regulations and University policies designed to protect the rights  
194 and welfare of research participants

195

196

#### 197 **Contacts and Questions:**

198

199 For questions, concerns, or complaints about the study you may contact our study manager at  
200 614-366-9693 or directly contact the Principal Investigator, Brittney Keller-Hamilton, at 614-  
201 366-9652.

202

203 For questions about your rights as a participant in this study or to discuss other study-related  
204 concerns or complaints with someone who is not part of the research team, you may contact  
205 the Office of Responsible Research Practices at 1-800-678-6251 or hsconcerns@osu.edu.

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207

208

#### 209 **Providing consent**

210

211 I have read (or someone has read to me) this page and I am aware that I am being asked to  
212 participate in a research study. I have had the opportunity to ask questions and have had them  
213 answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up  
214 any legal rights by agreeing to participate.

215

216

217

218 **Do you agree to be contacted about future research studies?** Please select one option:

219 **[Yes] [No]**

220

221

222 This document will be provided to you for your records.

223

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224 **Please click the button below to proceed and participate in this study. If you do not wish**  
225 **to participate, please close out your browser window.**  
226

Examining the Appeal of Nicotine Pouches in Ohio Appalachia  
NCT Number: NCT05236894  
Consent Approval Date: 05/31/2022

**The Ohio State University Consent to Participate in Research**

**Study Title: Examining the Appeal of Nicotine Pouches in Ohio Appalachia**

**Protocol Number: 2021C0199**

**Researcher: Brittney Keller-Hamilton, PhD, MPH**

**Sponsor: The Ohio State University**

**This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate.

**Your participation is voluntary.**

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. Your participation in this research study will not impact your affiliation with The Ohio State University in any capacity. You may withdraw from the study at any time.

**Purpose:**

Nicotine pouches are new smokeless tobacco products that are marketed as substitutes for cigarettes and are gaining in popularity. They may make a big impact in Ohio. There is little research on how nicotine pouches will be adopted. We want to better understand the appeal and potential impact of nicotine pouches on public health. There are two groups enrolling into this study. Participants enrolled in Aim 1 are from Ohio Appalachia and participants enrolled into Aim 2 can be from anywhere in Ohio. You are enrolling into Aim 2, which focuses on the differences between tobacco-derived and synthetic nicotine pouches. Participants can only enroll in one aim and not both.

We ask participants to provide blood samples for nicotine content analysis, which will show us how much nicotine is absorbed by your bloodstream as you use nicotine pouches. This is very helpful for us to understand how nicotine is absorbed by the body. Additionally, the questionnaires you answer will help us understand how and when you became a smoker, how much you like or dislike the nicotine pouches, and also how you feel while using nicotine pouches.

**Procedures/Tasks:**

This study will enroll 20 adult cigarette smokers from Ohio.

We invite participants to visit our lab for 3 study visits. You will be asked to abstain from all tobacco products for 12 hours before each visit to provide the study team with a baseline value of the nicotine levels in your blood. During each visit, you will be randomly assigned to

48 try a nicotine pouch provided by the study that contains either tobacco-derived or synthetic  
49 nicotine. All nicotine pouches used in this study can be purchased online or at stores. In other  
50 words, we did not make the nicotine pouches. You will keep the nicotine pouch in your mouth  
51 for 30 minutes. During this time, research staff will ask a series of questions and perform 7  
52 blood draws.

53  
54 During each visit, you will have an IV placed in one of your arms to make the series of blood  
55 draws less invasive. 3mL, or a little less than 1 teaspoon, of blood will be drawn at 7 intervals  
56 over the course of 90 minutes. The IV will be placed and blood draws will be performed by a  
57 trained research nurse.

58  
59 At the beginning of each visit, participants who are capable of becoming pregnant will be  
60 asked to take a urine pregnancy test. If you are found to be pregnant, you will be withdrawn  
61 from the study.

62  
63 You will be asked to try a nicotine pouch during each visit. As a participant, you will be asked  
64 to try 3 different types of nicotine pouches in random order. They are all FDA-approved and  
65 available in stores. Products include: Zyn wintergreen 3mg (tobacco-derived nicotine), a Fre  
66 wintergreen 3mg (synthetic nicotine), and a Niin wintergreen 3mg (synthetic nicotine).

67  
68 **Duration:**

69 This study involves 3 study visits. The study timeline for each participant will vary, however,  
70 each visit will take place 2 or more days after the previous visit and ideally within 2 weeks.  
71 We ask participants to complete all 3 visits within two months of enrollment.

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75 You may leave the study at any time. If you decide to stop participating in the study, there  
76 will be no penalty to you, and you will not lose any benefits to which you are otherwise  
77 entitled. Your decision will not affect your future relationship with The Ohio State  
78 University.

79  
80 **Risks and Benefits:**

81  
82 Every attempt will be made to reduce risk to you. Nicotine pouches are no more harmful than  
83 cigarettes and may even be less harmful. Questionnaires and blood collection involve minimal  
84 risk to you. The IV placed is similar to a routine blood draw that would be performed for a  
85 clinic visit. Potential risks are as follows: risk of using nicotine pouches, loss of  
86 confidentiality or privacy, potential for interrupting your plans to quit smoking, and slight risk  
87 of discomfort, bruising and infection with blood draw.

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89 You are not expected to directly gain any benefits from this study. Through your contributions  
90 to science, you provide insight into a new tobacco product that has potential to impact tobacco  
91 use in Ohio Appalachia. Moreover, data collected will inform public health efforts, policy,  
92 and clinical care in this region.

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94 While this trial is not without risk, every effort will be taken to reduce risk and undue burden  
95 on participants.

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97 Participating in this study might make it harder to quit smoking. If you plan to quit smoking  
98 in the next 3 months, you should not enroll in this study. We do not want to ask smokers who  
99 want to quit to continue smoking. Please ask our PI about any questions you may have about  
100 nicotine pouches, smoking, or smoking cessation.

101  
102 Study product use: It is important to note that nicotine pouches are no more harmful than  
103 cigarettes. If at any point you are uncomfortable with using the nicotine pouch, please notify  
104 study staff immediately.

105  
106 Slight risk of bruising, discomfort and infection with blood draw: Blood will be collected by  
107 trained research staff. Sterile instruments will be used and for blood draws, the participants  
108 skin will be cleaned with an alcohol wipe at the venipuncture site.

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110 Breach of confidentiality: All information linking your name to the study will be stored in our  
111 secure platform, REDCap or in a locked filing cabinet. You will be given a participant ID and  
112 all information collected will be stored under that ID. Your study information will be stored in  
113 the secure database, REDCap. Only trained members of the study team will have access to  
114 your data. Moreover, any paper documents regarding your visit will be stored in a locked  
115 filing cabinet with keys kept by the study PI and manager. Finally, your blood samples will be  
116 deidentified – meaning including your participant ID and not your name - and stored in a  
117 freezer in a locked room. While a breach of confidentiality is possible through hacking or  
118 another means of forced entry, we believe the risk is low.

119  
120 If you experience any bad reactions or issues as a result of this study, please report to our  
121 trained research nurse and study staff and, if severe, seek treatment immediately. Any  
122 treatment you seek as a result of this study will be covered by you.

123  
124

125 **Confidentiality:**

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127 We will work to make sure that no one sees your online responses without approval. But,  
128 because we are using the Internet, there is a chance that someone could access your online  
129 responses without permission. In some cases, this information could be used to identify you.

130  
131 Confidentiality will be maintained by numerically coding all data, disguising identifying  
132 information, and keeping data locked in file drawers or in a secure, password protected  
133 database. All biospecimen samples are kept in a locked freezer and also will be deidentified.  
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135 the information that connects participants' names and ID numbers. All electronic data will be  
136 numerically coded and stored in a password-protected database, on a password-protected  
137 computer in a secure research space. Participant information will be accessible only to

138 research staff, who are pledged to confidentiality and have completed training in the ethical  
139 conduct of research. Identifying information will not be reported in any publications.

140

141 Also, there may be circumstances where this information must be released. For example,  
142 personal information regarding your participation in this study may be disclosed if required by  
143 state law. Also, your records may be reviewed by the following groups (as applicable to the  
144 research):

- 145 • Office for Human Research Protections or other federal, state, or international  
146 regulatory agencies;
- 147 • The Ohio State University Institutional Review Board or Office of Responsible  
148 Research Practices;
- 149 • Authorized Ohio State University staff not involved in the study may be aware that  
150 you are participating in a research study and have access to your information; and
- 151 • The sponsor, if any, or agency (including the Food and Drug Administration for FDA-  
152 regulated research) supporting the study.

153

154 Your de-identified information may be used or shared with other researchers without your  
155 additional informed consent. Your deidentified blood samples may be sent to an outside lab  
156 for analysis. Your name would never be connected with the sample.

157

158 We will not recontact you every time we use your sample or data from the questionnaires for  
159 analysis.

160

#### 161 **Future Research:**

162

163 You will be given the option to be contacted for future, related studies.

164

165 Your selection for being contacted about related studies will not impact your eligibility for  
166 this study.

167

168

#### 169 **Incentives:**

170 By law, payments to participants are considered taxable income. You may receive up to \$350  
171 for your participation. After each visit, you will receive \$100 on a pre-paid ClinCard. If you  
172 complete all of your visits in a month, you will receive a \$50 bonus at the end of your third  
173 visit. If it is not possible for you to perform study procedures during your visit, we will  
174 provide \$50 on a pre-paid ClinCard to thank you for your time.

175

176

177

#### 178 **Participant Rights:**

179 You may refuse to participate in this study without penalty or loss of benefits to which you  
180 are otherwise entitled. If you are a student or employee at Ohio State, your decision will not  
181 affect your grades or employment status.

182

183 Additionally, if at any point you decide to quit tobacco and/or nicotine products, please let us  
184 know and we will withdraw you from our study. If you wish to withdraw from the study,  
185 please contact the program manager Hayley Curran by phone or email and state your desire to  
186 withdraw from the study. Our phone number is 614-366-9693 and our lab email is BKH-  
187 Lab@osumc.edu If you withdraw, data you previously provided to the study may have  
188 already been used for analyses or publication; however, no new information will be accessed  
189 or analyzed from the time of withdrawal onward.

190

191 If you choose to participate in the study, you may discontinue participation at any time  
192 without penalty or loss of benefits. By agreeing to participate, you do not give up any  
193 personal legal rights you may have as a participant in this study.

194

195 An Institutional Review Board responsible for research involving human subjects at The Ohio  
196 State University reviewed this research project and found it to be acceptable, according to  
197 applicable state and federal regulations and University policies designed to protect the rights  
198 and welfare of research participants

199

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#### 201 **Contacts and Questions:**

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203 For questions, concerns, or complaints about the study you may contact our study manager at  
204 614-366-9693 or directly contact the Principal Investigator, Brittney Keller-Hamilton, at 614-  
205 366-9652.

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207 For questions about your rights as a participant in this study or to discuss other study-related  
208 concerns or complaints with someone who is not part of the research team, you may contact  
209 the Office of Responsible Research Practices at 1-800-678-6251 or hsconcerns@osu.edu.

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216 participate in a research study. I have had the opportunity to ask questions and have had them  
217 answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up  
218 any legal rights by agreeing to participate.

219

220

221

222 **Do you agree to be contacted about future research studies?** Please select one option:  
223 **[Yes] [No]**

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229 **to participate, please close out your browser window.**  
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