

## **Informed Consent Form (ICF)**

**Official Title:** Brief Intervention Combined With Health Coaching Via Social Media for Cannabis Use

**Document Date:** 06/07/2021

**NCT number:** NCT04316741

## UNIVERSITY OF MICHIGAN AND HURLEY MEDICAL CENTER CONSENT TO BE PART OF A RESEARCH STUDY

### 1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

**Study title:** SnapCoach

**Company or agency sponsoring the study:** National Institutes of Health

**Principal Investigator:** Erin Bonar, PhD, Department of Psychiatry, University of Michigan

**Study Coordinator:** Emily Sweezea, BA, Department of Psychiatry, University of Michigan

#### 1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to give consent. Before you do, be sure you understand what the study is about.

**Please read carefully Section 5.1 and Section 9.1, regarding the confidentiality and security risks.**

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about health conditions and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time. Research studies do not always offer the possibility of treating your condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. For instance, if you are currently on probation or parole there could be increased risk to your status if there was a breach of confidentiality. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Flint or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research collects health-related information to better understand young people's own health behaviors, substance use, and social media use. The research will help us learn about how the mobile app Snapchat can be used to collect and share information about health behaviors by receiving feedback from participants about their experiences with having a conversation with a health coach and receiving health information over Snapchat for four weeks after enrollment.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include feeling uncomfortable with answering some personal questions. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by improving health programs for people by using new ways to communicate health information. We expect the amount of time you will participate in the study will be up to about 1 and a half hours for the first set of activities, varied times to view and reply on Snapchat over the next four weeks, and about 25 minutes in 1-month for the follow-up survey, and about 1 hour in 3-months for the follow-up interview.

You can earn up to \$105 for completing these activities. You can decide not to be in this study. Alternatives to joining this study include receiving standard care.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

## 2. PURPOSE OF THIS STUDY

### 2.1 Study purpose:

The purpose of this study is to learn about how the app Snapchat can be used to collect and share information on health behaviors, such as social media use and substance use, and well-being. We are asking 18-25 year olds to interact with a health coach as well as receive Snapchat message content, to help us learn how we can improve *SnapCoach*.

## 3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. If you choose to participate, this will not affect your medical care today or in the future. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

### 3.1 Who can take part in this study?

To take part in this study you must be between the ages of 18 and 25 and have completed the screening survey.

### 3.2 How many people are expected to take part in this study?

We expect to enroll about 100 people in this study.

## 4. INFORMATION ABOUT STUDY PARTICIPATION

### 4.1 What will happen to me in this study?

If you decide to participate in the study, this is what will happen

- You will be asked to complete a baseline survey. This includes a 15-minute online survey that asks questions about your background, mental health and substance use, followed by a 15 to 20-minute interview with research staff where we'll ask more questions about your health behaviors over the past month.
- You will be asked to provide a urine sample for drug testing if enrolling in-person. Study staff will record the results of the test, then your sample will be thrown away. The results of your test will not be shared with anyone outside of the study, including parents or medical staff.
- You will then be randomly assigned (like flipping a coin) to one of the study groups and asked to receive *SnapCoach* messaging on Snapchat for the next four weeks. You will receive up to three different Snapchat messages per day. You will be asked to accept *SnapCoach* as a friend on snapchat and watch introduction videos of the SnapCoach team who you will be snapping with. You must also agree to follow the rules of our Snapchat User Safety Agreement, which we will review when it is time to add us on Snapchat. The groups are:

**Group 1:** You will meet with a research health coach for about 30-45 minutes for a brief video-chat or in-person conversation to talk about your goals, health behaviors, different ways you can reach your goals, and review community resources together. The session will be audio recorded (voice only) and you can

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give your permission for that later in this form. You may still take part in the study if you don't want to be audio recorded. You will then be asked to test *SnapCoach* messaging on Snapchat for four weeks where you will receive up to three different Snapchat messages per day over the next 4 weeks. The *SnapCoach* team will share health information focused on well-being and health behaviors.

**Group 2:** You will review community resources with the study team member, and be asked to test *SnapCoach* messaging on Snapchat for four weeks where you will receive up to three different Snapchat messages per day over the next 4 weeks. The *SnapCoach* team will share news and other information about things like entertainment, weather, and current events.

As part of these activities, you will then complete a 3 to 5-minute post-test survey giving your feedback about your experience with *SnapCoach* today.

While snapping with the *SnapCoach* team over four weeks, we encourage you to reply to *SnapCoach* messages. The *SnapCoach* team will only be available at certain times to respond to you – if you have a crisis, do not contact *SnapCoach* because we may not reply immediately. Please contact 911 or other emergency services listed in the resources we will provide to you.

In about 1-month, you will be asked to complete a 1-month follow-up survey online, over the phone, or in-person, answering questions similar to those in today's survey along with giving your feedback on *SnapCoach* messaging.

Lastly, in about 3-months, you will be asked to complete a 3-month follow-up survey in-person, online, or over the phone, answering questions similar to those in today's survey, followed by a staff-delivered assessment where we'll ask more questions about your health behaviors over the past two months. You will also be asked to provide a urine sample for drug testing (for in-person follow-ups).

By signing this form, you also give permission for the study team to look at your medical record for information about your recent visit in the Emergency Department (ED). We will collect information including the reason for the visit and to access any updated contact information listed in your medical record for use of contacting you for the surveys mentioned above.

#### **4.2 How much of my time will be needed to take part in this study?**

If you are in Group 1, the baseline survey, interview and urine drug test (if in-person) and meeting with a health coach will take about 1 and a half hours to complete. If you are in Group 2, today's baseline survey, interview, and urine drug test (if in-person) will take about 1 and a half hours to complete. The amount of time you spend reviewing *SnapCoach* messages during the 4 weeks of Snapchat messaging is up to you. The 1-month follow-up survey takes about 25 minutes to complete. The 3-month follow-up survey takes about 1 hour to complete.

#### **4.3 When will my participation in the study be over?**

Your participation in the study will be over after you complete the 3-month follow-up survey.

#### **4.4 What will happen with my information and/or biospecimens used in this study?**

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Biospecimens will not be collected, stored, or shared outside of the study. Once the urine drug screens are completed the container used for collection will be disposed of by research staff.

Your collected information and biospecimen results may be shared with the sponsor of this study (National Institutes of Health).

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

The information we collect from you will be stripped of identifiers (meaning any information that would identify you, like name or email, would be removed) and may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

## 5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

### **5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?**

Some of the questions we ask are about sensitive or personal information such as your mental health or drug use. Sometimes these questions can make you feel uncomfortable or upset. You don't have to answer any questions you don't want to and you can leave the study at any time.

There is a possibility of loss of privacy/confidentiality. To protect your privacy during in-person and telephone/online meetings we will make sure that no one can overhear the conversations in the first set of activities and at community follow-up locations when necessary. However, there is a possibility that others may see or hear your open smart phone communications when accessing and sending study messages in public places or when you are not alone. In addition, it is possible that private messaging from a mobile device may be spied on, intercepted or hacked during transmission. We encourage you to use a strong password or passcode on your phone to help reduce any privacy-related issues concerning the study messages on your personal phone. We urge you not to read or text responses to study messages while driving. Wait until you are in a safe and private place before responding to study-related messages.

We will do everything we can to protect your identity and keep your answers confidential, except as noted in section 9.1. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

### **5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?**

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any problems that you have during this study.

### **5.3 If I take part in this study, can I also participate in other studies?**

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

### **5.4 How could I benefit if I take part in this study? How could others benefit?**

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

**5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?**

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

**6. ALTERNATIVES TO PARTICIPATING IN THE STUDY**

**6.1 If I decide not to take part in this study, what other options do I have?**

Participating in this study is voluntary. Choosing not to participate will not affect your medical care in any way.

**7. ENDING THE STUDY**

**7.1 If I want to stop participating in the study, what should I do?**

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

**7.2 Could there be any harm to me if I decide to leave the study before it is finished?**

We do not expect that you would experience any harm if you decide to leave the study before it is finished.

**7.3 Could the researchers take me out of the study even if I want to continue to participate?**

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

**8. FINANCIAL INFORMATION**

**8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?**

Taking part in this study will not cost you anything. As with any cell phone, depending on your text/data plan, you may be charged for text/data use on your personal phone bill.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

**8.2 Will I be paid or given anything for taking part in this study?**

You will receive these amounts for completing each survey and activities listed.

Study Activity	Total Amount
Baseline survey, interview, urine drug test (if in-person) and add <i>SnapCoach</i> on Snapchat	\$40
1-month survey	\$25
3-month survey, interview and urine drug test	\$40
<b>Study Total:</b>	<b>\$105</b>

### 8.3 Who could profit or financially benefit from the study results?

No person or organization has financial interest in the outcome of this study. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

### 9.1 How will the researchers protect my information?

You may be worried about the privacy of your answers. We won't share your answers with anyone except the researchers of this study. We will ask for your contact information so that we can contact you about the study. Your surveys will be coded with a unique number and stored in a different location from this collected contact information. This will prevent someone other than researchers to know that the survey answers are yours.

The computerized surveys are designed and administered using Qualtrics Research Suite through the University of Michigan (<http://www.qualtrics.com/>). Qualtrics meets the rigorous privacy standards imposed on health care records by the Health Insurance portability and Accountability Act (HIPAA). There are security precautions in place to protect against unauthorized access, but there is still the possibility of unauthorized access. No identifying information is directly linked to your answers. For more information, Qualtrics security and privacy statements can be found at <http://www.qualtrics.com/security-statement> and <http://www.qualtrics.com/privacy-statement>.

All study tablets and cell phones used for collecting survey answers and to communicate with participants will be password protected, use UM encryption, when possible, and only be accessed by study staff. For the session with a health coach in group 1, or for other surveys you choose to complete in this way, we will use a video chat platform (such as Facetime, BlueJeans, Vidyo, or Skype for Business). Your activity on Snapchat is still accessible to Snapchat and subject to the app's terms of use. We encourage you to use a strong password/code on your phone (mix of lower case and upper case letters, numbers, and symbols) and to view study messages in private spaces. **Your confidentiality will be kept to the degree permitted by the technology being used. No guarantees can be made regarding interception of Snapchat, video chat, and/or other online communications or information by any third parties.** When using video chat, it is possible you could be automatically recorded by the platform (such as Facetime), similar to when you use these platforms in everyday life. Although every reasonable effort

has been taken, confidentiality during actual web-based phone, or video chat communication procedures cannot be guaranteed.

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 them 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 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.

When your survey answers and audio files are collected, they are labeled with a number. Survey answers and audio files are stored separately from your name, phone number or other information that might let someone other than the researchers connect the information to you. You will be asked during audio recorded sessions to try not to say your name or any information that would allow someone to determine who you are from the audio recording. Study paper forms are stored in locked file cabinets. Computer files are saved with passwords. You will not be identified in any reports on this study.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## **9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?**

Consenting to this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- All records relating to your condition, the treatment you have received, and your response to the treatment

- Demographic information (e.g.-race, ethnicity, gender)
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders may need the information to:
  - Make sure the study is done safely and properly
  - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

### **9.3 What happens to information about me after the study is over or if I leave the study before it is finished?**

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have left the study.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at <http://www.uofmhealth.org/patient+and+visitor+guide/hipaa>. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

### **9.4 When does my permission to use my PHI expire?**

Your permission will not expire unless you cancel it.

## 10. CONTACT INFORMATION

### 10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report a problem
- Leave the study before it is finished
- Express a concern about the study

**Principal Investigator:** Erin Bonar, PhD

Mailing Address: 2800 Plymouth Road  
Ann Arbor, MI 48109-2800

Telephone: 734-764-7936

**Study Contact:** Bailey Boyle

Mailing Address: 2800 Plymouth Road  
Ann Arbor, MI 48109-2800

Telephone: 810-262-4874

**You may also express a question or concern about a study by contacting the Institutional Review Board listed below:**

University of Michigan Medical School  
Institutional Review Board (IRBMED)  
2800 Plymouth Road  
Building 520, Room 3214  
Ann Arbor, MI 48109-2800  
Telephone: 734-763-4768  
Fax: 734-763-1234  
e-mail: [irbmed@umich.edu](mailto:irbmed@umich.edu)

Hurley Medical Center  
Institutional Review Board  
1 Hurley Plaza  
Flint, MI 48503-5993  
Telephone: 810-262-9974  
Fax: 810-262-9587

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

*When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

## 11. RECORD OF INFORMATION PROVIDED

### 11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (Note: *In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.*)

## 12. SIGNATURES

### Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with \_\_\_\_\_. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Signature: \_\_\_\_\_ Date (mm/dd/yy): \_\_\_\_\_

### Consent to audio recording solely for purposes of this research

This study involves audio recording. If you do not agree to be recorded, you can still take part in the study.

Yes, I agree to be audio recorded.

No, I do not agree to be audio recorded.

Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date (mm/dd/yy): \_\_\_\_\_

### Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_ Date (mm/dd/yy): \_\_\_\_\_