



RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

Protocol Title:

A Real-time, Contextual Intervention Using Mobile Technology to Reduce Marijuana Use among Adolescents and Young Adults. The MOMENT Study

Principal Investigator:

Dr S. MD, MPH

Why is this study being conducted? What is its purpose?

We are conducting this research study (the MOMENT study) to evaluate an approach to help adolescents and young adults who use marijuana frequently to reduce their use.

Who is conducting this study and where is it being conducted?

The study is being conducted by Dr. S and her associates in the Adolescent/Young Adult Medical Clinic at Boston Children's Hospital (BCH) and the Adolescent Clinic at the Martha Eliot Health Center (MEHC). The study is funded by the National Institute on Drug Abuse, which is part of the National Institutes of Health.

How are individuals selected for this study? How many will participate?

We are asking patients of the BCH Adolescent/Young Adult Medicine Clinic and the MEHC Adolescent Clinic who are ages 15 to 24 years and use marijuana regularly (3 or more times a week) to participate in this study. If you agree to volunteer, you will be one of approximately 108 young people who participate.

What do I have to do if I am in this study?

The MOMENT Study has a total of 6 study visits over 4½ months.

Study Visit 1:

At the first study visit, we will ask you to complete a survey using a computer and headphones to hear the survey being read to you. The survey will include questions about yourself, like your age, your grade, your work experience, and your family background. We will also ask you questions on your use of marijuana, why you use it, and how it affects you. The survey will take about 15-30 minutes.

After the survey, we will give you a calendar of the previous 30 days and ask you to record on it on which days you used marijuana, as well as alcohol or other drugs. We will ask you to describe some details about your most recent day of marijuana use, including who you were with, where you were, why you used marijuana and how much, etc.



Pt Name: _____

Then, we will teach you how to use the smartphone to complete reports. If you have your own smartphone and it is compatible with the study survey application, we will place the application on your phone. If you do not have a smartphone compatible with the study survey application, we will loan you a smartphone to use to make the reports. The smartphone will be set to signal approximately 4-6 times a day, prompting you to complete a report. On these reports, we will ask you to answer questions about where you are, who you are with, how you are feeling, and your recent use of marijuana and other drugs. We will ask you when you usually wake up and go to sleep, and we will set the smartphone to signal only when you are typically awake. You will also be able to turn off the signal in advance of specific times when you know that you would prefer to not be signaled, such as when you are taking a test. In addition to answering questions when you are signaled, we will also ask you to fill out a daily diary report about the events of your day, symptoms you may have had, and a summary of your marijuana use and avoidance of use. We will ask you to choose a set time to complete the daily diary report each day. You will choose a 4-digit password that you will have to enter before starting each report. The password is put in place for your privacy. We will show you how to enter the password and fill out the reports. The smartphone training will take about 30 minutes.

We will ask you for contact information, such as your telephone number and e-mail address, so that we can check in with you about how using the smartphone is going and remind you about study visits. You may choose not to provide all of this contact information. Your contact information will be kept confidential. We will contact you by phone, e-mail, or text message (according to your preference) 1-2 days after Study Visit 1 to see how using the smartphone to make reports is going; 1-3 days before each Study Visit (after Study Visit 1) to remind you of each upcoming visit; twice a month for the three months between Study Visits 4 and 5 to check in with you and to make sure that we have your up-to-date contact information. If we are contacting you by phone, we will not reveal the purpose of the call if someone other than you answers the phone. We will confirm your identity using a password that you choose.

Study Visit 2:

After you have completed the smartphone reports for one week, we will ask you to come back to the clinic for Study Visit 2. If you have been using a study smartphone, we will ask you to bring it with you so that you can return it to us at this visit. During Study Visit 2, you will meet with a counselor for your 1st of 2 sessions. The counselor will talk with you about your life in general and what is important to you now and in the future, and about your marijuana use. The counselor will audio record the interview. The purpose of the audio recording is so that we can evaluate the counselor. Study Visit 2 will last about an hour.

Study Visit 3:

One week after Study Visit 2, we will ask you to return to the clinic for Study Visit 3. At Study Visit 3, you will meet with the counselor for the 2nd of your 2 sessions. The counselor will help you to develop a plan for reducing your marijuana use. As for Study Visit 2, the counselor will audiorecord the interview for evaluation purposes. Study Visit 3 will last about an hour.

At the end of Study Visit 3, you will be randomly assigned (like the flip of a coin) to one of three groups: Counseling, Counseling plus Self-Monitoring, or Counseling plus Self-Monitoring with Messaging.



Pt Name: _____

- If you are in the Counseling group, you will be asked to return to the clinic in two weeks for Study Visit 4.
- If you are in the Counseling plus Self-Monitoring group, you will be asked to use a smartphone to complete reports in response to signal prompts 4-6 times a day and a daily report once a day for two weeks, then return to the clinic for Study Visit 4. As for Study Visit 1, if you do not have a smartphone compatible with the study survey application, we will loan you a smartphone to use to make the reports.
- If you are in the Counseling plus Self-Monitoring with Messaging group, you will be asked to complete reports in response to signal prompts 4-6 times a day and a daily report once a day for two weeks, then return to the clinic for Study Visit 4. You will receive messages on the smartphone during the reports. As for Study Visit 1, if you do not have a smartphone compatible with the study survey application, we will loan you a smartphone to use to make the reports.

Study Visit 4:

Two weeks after Study Visit 3, we will ask you to return to the clinic for Study Visit 4. If you have been using a study smartphone, we will ask you to bring it with you so that you can return it to us at this visit. We will ask you to fill out a 14-day calendar about your use of marijuana, alcohol, and other drugs. We will also ask you questions regarding your study participation, including how it was to meet with the counselor, complete the study assessments, and use the smartphone, and about any difficulties you may have had. Study Visit 4 will last about 30 minutes.

Study Visit 5:

Three months after Study Visit 4, we will ask you to come back to the clinic for Study Visit 5. We will ask you to fill out another computer survey and a calendar about your use of marijuana, alcohol, and other drugs in the previous 30 days. You will be asked to use a smartphone to complete reports in response to signals 4-6 times a day and a daily diary report for one week. If you do not have a smartphone compatible with the study survey application, we will loan you a smartphone to use to make the reports. Study Visit 5 will last about 45 minutes.

Study Visit 6:

One week later, we will ask you to return to the clinic for Study Visit 6. If you have been using a study smartphone, we will ask you to bring it with you so that you can return it to us at this visit. We will ask you on a computer survey and in an interview questions about your marijuana use and about your study participation as a whole. The survey and interview will take about 30 minutes to complete.

The next page shows a figure of the MOMENT study activities by study visit.



Pt Name: _____

MOMENT Study Activities by Study Visit

Study Visit Number	1	2	3	4	5	6
Study Activity						
Computer survey	✓					
Calendar	✓					
Training	✓					
Counseling						
Self-monitoring reports		A, B, C				
Daily reports						
Messages						
Feedback from you		✓		✓		
Payment		✓		✓		
Week in Study (interval)	0	1 wk	1 wk	2 wks	3 mos	1 wk
			2		16	17

✓ = All participants, A = Counseling group, B = Counseling plus Self-Monitoring group, C = Counseling plus Self-Monitoring with Messaging group, ← → = activity occurring between indicated study visits

If you are under age 18: Even though parental permission is not required for participating in this study, we encourage you to talk about your participation in this study with a parent or another adult if you feel that you would like them to know about the study, or if you feel that you need their advice for any reason.

What are the risks of this research study? What could go wrong?

You may be uncomfortable with some of the questions we will be asking you to answer. If you feel uncomfortable at any point, we encourage you to let the researcher know. If you have any questions or concerns after you finish the interview, you are welcome to contact the researcher at any point.

It is possible that someone may learn about your marijuana use as a result of you being in this study. We will make every effort to minimize the risk of this happening. We will only meet with you about the study in a private space in or near the clinic. After we have typed up what you and the counselor said, the audio recordings will be destroyed. The computer and paper assessments you complete during the study will not have your name on them. The smartphone and the reports on the smartphone will also not have your name on them.

You may receive a smartphone report signal when you are not able to complete a report. To minimize the chances of this happening, the smartphone will allow you to silence it in advance for up to 3 hours. If you have not informed your parent or guardian about the study, you may feel uncomfortable or get in trouble if they find the smartphone and ask you about it. Other people may also see the computer and have questions about it. We encouraged you to think carefully about whether your participation in this study would raise problems for you at home, school, work, or elsewhere. While you are participating in this study, you are still expected to follow the cell phone policies of your school, workplace, or other locations where you may be during the study.



Pt Name: _____

We will provide you with a card to give to anyone you wish if you feel a need to explain that you are participating in a research study. The card will say, "A Children's Hospital research study" and the name and telephone number of the research assistant. If anyone calls, the research assistant will confirm that you are, in fact, participating in a research study; however, no other information will be provided to the caller about you or the research. If a problem with having the smartphone does arise in school, work, home, or elsewhere, we will discuss the nature of the problem with you and together we will develop a plan with you, which may include programming the smartphone to signal on a different schedule or discontinuing your participation in the study. The smartphone is an electronic device that may be seen as desirable by others. You should not show the smartphone or complete a report if you are ever concerned that someone might wish to take the smartphone from you. It is possible that another person might harm you to take the smartphone. In the event that a person attempts to take the smartphone, you should simply hand it over. Your safety is the top concern. If you were loaned a smartphone to use for the study, you will not be held responsible if it is lost, stolen, or damaged.

What are the benefits of this study?

You may receive a direct benefit since there is the possibility that you may reduce your marijuana use as a result of participating in the study. In addition, the data we collect will assist us in developing better tools to help young people make healthy choices about using marijuana and other drugs.

Are there costs associated with this study? Will I receive any payments?

There are no costs associated with participating in this study. If you agree to participate, we will offer you payments at the end of Study Visits 2, 4, and 6. The amount of the payments will depend on the study activities you complete. Payment will not depend on *what* you report on the assessments, just *whether* you complete them. Payment will be made in the form of a gift card to a store of your choosing from a list we will show you.

At the end of Study Visit 2, you will be offered up to \$50:

- \$15 for completing assessments during Study Visit 1,
- \$10 if you complete at least 50% of the smartphone reports, \$20 if you complete at least 80% of the smartphone reports (between Study Visits 1 and 2), and
- \$15 for completing the first counseling session (Study Visit 2).

At the end of Study Visit 4, you will be offered up to \$50:

- \$25 for completing the second counseling session (Study Visit 3)
- \$25 for completing assessments during Study Visit 4

At the end of Study Visit 6, you will be offered up to \$50:

- \$15 for completing assessments during Study Visit 5
- \$10 if you complete at least 50% of the smartphone reports, \$20 if you complete at least 80% of the smartphone reports (between Study Visits 5 and 6), and
- \$15 for completing assessments and exit interview (Study Visit 6).



Pt Name: _____

In addition, at the end of each study visit, we will offer you reimbursement for expenses associated with travel. Travel reimbursement will be in the form of 2 Charlie Cards or, for participants at the Children's Hospital clinic, a validated parking ticket.

What will happen with the information obtained as part of this study? What about confidentiality?

We are committed to protecting your identity. Your name will not be voluntarily released to anyone not connected with the project. Your name will not be revealed in any published reports of the study. All study records will be private and will be kept locked up. Your responses to the questions will be identified by number. Your name will not be on any study forms.

You may choose to voluntarily release information about yourself or your involvement in this interview. In addition, there are situations in which the researchers may voluntarily disclose information that would identify you as a participant in the research project, without your consent. This would occur under the following circumstances: if the researchers are concerned that you may be suicidal (thinking about killing yourself), or otherwise at immediate risk for seriously harming yourself or others (carrying weapons, selling of drugs), they will need to notify your primary care provider or counselor and/or involve your parents or guardians according to standard clinic practice. If, during your participation, we learn about serious harm to you or someone else, such as child abuse, we will take steps to protect you or other people, including notifying the Department of Children and Families or other authorities. Finally, if researchers become aware of a serious and/or dangerous drug abuse problem they will notify your primary care provider or counselor and/or involve your parents or guardians according to standard clinic practice.

The information you give us during the visits and a copy of this informed consent will not be placed in your medical record. A copy of this form and the information you give us will be kept in a separate research file maintained by the Principal Investigator, Dr. S Therefore, it will be unlikely that others within the hospital, an insurance company, or an employer would ever learn about your participation. However, to complete enrollment in the study, a member of the study staff will contact your clinic provider to make sure that he or she is aware of your interest in participating in this study. Your provider will be asked to discuss your eligibility for the study, as well as any possible risk to you as a result of participating in the study. Any correspondence and information obtained from your provider will be kept confidential, and will not be included in your medical record.

We have a Certificate of Confidentiality from the US Government. It adds special protection for research information that identifies you. It says we do not have to identify you, even under a court order or subpoena. Still, we may report medical information (if you need medical help), probable harm to yourself or others, or probable child abuse or neglect, and the government may see your information if it audits us. This Certificate does not mean the government approves or disapproves of our project.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your



Pt Name: _____

family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

If I do not want to take part in this study, what are the other choices?

The alternative to participating in this interview is not participating in the study. You can still talk about your marijuana use with and get help reducing your use from your regular medical provider or other staff in the clinic.

What are my rights as a research participant?

Participation in this study is voluntary. If you choose not to participate, your decision will not affect your receiving medical care in any way. You may withdraw from the study at any time.

Why would I be taken off the study?

If the researcher is concerned that you are becoming distressed or getting in trouble as a result of your study participation, she may recommend that you stop participating in the study. You may also be taken off the study if you are unable to attend the study visits required by the study or otherwise not able to follow the study requirements. If you choose to withdraw from the study and you still have a study smartphone, we will ask you to come to the clinic to return the smartphone. If you are not able to come to the clinic, we will send you a pre-paid mailer for you to return the smartphone by mail.

What information do I need to know about the Health Insurance Portability and Accountability Act (HIPAA)?

During this research, information about you will be collected. In general, under federal law, information about patients is private, but there are exceptions and you should know who will have access to this information and might see it.

Researchers may be collecting information about you from medical records. They may also learn things from procedures that are part of the research itself such as tests, office visits, questionnaires and interviews.

The following people will be able to see this information:

- As HIPAA permits, medical and research staff at Children's Hospital, including people listed on your informed consent.
- Medical staff who are directly involved in your care that is related to the research or arise from it.
- People who oversee, advise or conduct research at Children's Hospital, and people who oversee or evaluate research and care, including the Committee on Clinical Investigation, staff working on quality improvement, and other clinicians and administrative staff of Children's Hospital.



Pt Name: _____

- People from agencies and organizations that provide independent accreditation and oversight of research
- Sponsors or others involved in funding the research.
- Federal agencies that oversee or review research information.

You should be aware that the federal privacy rule does not cover all of these possible uses. This means that once some of the above mentioned users receive your health information they do not have to follow the same rules. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Children's Hospital Privacy Officer atxxx-xxx-xxxx.

There is no set time for destroying this information and no time limit for its use. Researchers continue to analyze date for many years and it is not possible to know when they will be done.

You do not have to sign this form. If the form is not signed, however, you won't be able to participate in the study. Not signing will not affect your care at Children's Hospital in any way now or in the future. Also, there will be no penalty or loss of benefits if you choose not to sign and participate.

You also have the right to withdraw from this study at any time. You have the right to end your permission for Children's Hospital to use or share the protected information about you that was collected as part of the research.

Researchers may also continue to use information already collected to protect the integrity of the study. This means that your withdrawal won't make the whole study useless. Once you remove your permission and you are no longer in the study, no more private health information will be collected. If you wish to withdraw you will need to do so in writing. Your investigator will have a form for you to use. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information.

Although there are some legal limitations, you have the right to get protected information resulting from this research that relates to your treatment or to payments. This information is available after the study analysis is done. To request the information, please contact the Hospital's Privacy Officer at 617-355-5502. If you have questions, please be sure to ask for answers.

Research at Children's Hospital: Children's Hospital has recently developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's Hospital, please visit the program at www.researchchildren.org

Children's Hospital is interested in hearing your comments, answering your questions and responding to any concerns regarding clinical research at Children's Hospital. If you would like further information about the type of clinical research performed at the Hospital or have suggestions, questions or concerns regarding clinical research you may send an e-mail to ccr@childrens.harvard.edu or call 617 355-7052 between the hours of 8:30 and 5:00 PM.



Pt Name: _____

CONSENT/AUTHORIZATION:

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

<input type="checkbox"/> I can call ...	<input type="checkbox"/> At ...	<input type="checkbox"/> If I have questions or concerns about ...
Investigator: Dr. S MD, MPH		
	Phone: 617-355-XXXX Pager: 617-XXXX Pager ID: XXX	<ul style="list-style-type: none">▪ General questions about the study▪ Research-related injuries or emergencies▪ Any research-related concerns or complaints
Study Contact: Assistant	Phone: 617-355-XXXX Pager: 617-355XXXX Pager ID: XXXX	<ul style="list-style-type: none">▪ General questions about the study▪ Research-related injuries or emergencies▪ Any research-related concerns or complaints
Office of Clinical Investigations	Phone: 617-355-7052	<ul style="list-style-type: none">▪ Rights of a research subject▪ Use of protected health information▪ Compensation in event of research-related injury▪ Any research-related concerns or complaints▪ If investigator/study contact cannot be reached▪ If I want to speak with someone other than the Investigator, Study Contact or research staff

I have been satisfactorily informed of the above-described procedure with its possible risks and benefits. I have been provided with the applicable Privacy Rule provisions under the Health Insurance Portability and Accountability Act. I give permission for my participation in this study and for use of the associated protected health information as described above.

I understand that participation in this study is voluntary. If I refuse to participate or choose to drop out of the study at any time, I understand there will be no penalty or loss of benefits to which I am otherwise entitled, and this decision will not affect present or future care by the doctors or the hospital. I am signing this consent form before participating in any research activities. I have been given a copy of this form.

Date (MM/DD/YEAR) Signature of Participant or Legally Authorized Representative

INVESTIGATOR'S AND/OR ASSOCIATE'S STATEMENT:

I have fully explained to all involved parties (participant/parent/guardian as applicable) the nature and purpose of the above-described procedures and the risks involved in its performance. I have provided the subject/family with the Privacy Rule if requested. I have answered and will answer all questions to the best of my ability. I will inform the participant of any changes in the procedures or the risks and benefits if any should occur during or after the course of the study.



Pt Name: _____

I have given a copy of the consent/ authorization form to the subject/family



Date (MM/DD/YEAR)

Signature of **Investigator or Associate**

WITNESS SIGNATURE REQUIRED BELOW ONLY IF: (check which one applies)

- the consent document needs to be read to subject or legal representative **or**
- communication impairments limit the subject's ability to clearly express consent **or**
- required by sponsor/CCI.
- other reason: please specify _____

I confirm that the information in this consent form was accurately explained to, and understood by the subject or legally authorized representative, and that informed consent was given freely.



Date (MM/DD/YEAR)

Signature of **Witness**