Title: Pilot Trial of Contingency Management for Long-Term Cannabis Abstinence
NCT number: 03786224
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Subject Identification

Protocol Title: Contingency Management for Six Months of Cannabis Abstinence among Adolescents

Principal Investigator: Randi Schuster, PhD

Site Principal Investigator:

Description of Subject Population: Healthy High-School Aged Adolescents with Cannabis Use

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

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.

Why is this research study being done?

The purpose of this research study is to learn about how a number of different variables may influence adolescents’ thinking abilities. One of the goals of this study is to better understand how abstaining from cannabis for six months may affect one's emotions, behaviors, and thinking abilities.

We are asking you to take part in this research study because you are a healthy, high school-aged adolescent over the age of 18 who uses cannabis and is enrolled in a school participating in this project.

About 20 adolescents will take part in this pilot research study.

How long will I take part in this research study?

It will take 26 visits to complete this research study, which will be conducted over approximately six months (or 24 weeks). Visits will last anywhere between 10 minutes and 2 hours.

What will happen in this research study?

Each of the 26 visits will occur at the participating school at which you are enrolled and we will schedule the visits based on your individual schedule. We will not remove you from your academic classes and will try to arrange a schedule that is as minimally intrusive as possible (e.g., during lunch, free periods, before/after school).

During the visits (ranging from approximately 10 minutes to 2 hours per visit), we will ask you to:

- Fill out questionnaires that ask about topics such as personality, mood, social group, health, and drug and alcohol use.
- Complete interviews about cannabis and other substance use as well as mood.
- Provide a urine sample to check for drug use.
    - This urine drug screen will not become part of your medical record.

We will ask you to <u>stop</u> using cannabis after the first visit through the end of the last, twenty-sixth visit (total of approximately 6 months without cannabis use). We will also ask that all participants refrain from the use of illicit drugs and the consumption of alcohol on the day of every study visit.

Optional (not required) Saliva Samples for Genetic Testing: The collection of a saliva sample for genetic research is optional (not required). You can still take part in the main study even if you don't want to take part in the genetic study. DNA is your genetic material, the material from which your genes are made. Your genes are inherited from your parents and passed on to your children. Genes can teach us about important things that influence your health. Giving a DNA sample involves filling 1-2 small plastic containers with your saliva. This will be done at your first visit and should take less than 10 minutes. Your saliva sample will be labeled with a code number and not with your name or other identifying information. The coded sample will be sent to our lab at MGH, DNA will be removed and analyzed to help us find genes that may play a role in cognitive abilities related to cannabis use. A coded portion of your DNA sample will be used for whole genome analysis. Usually researchers study a few areas of your genetic code that are linked to a disease or condition. In our whole genome analysis, we will be using all or most of your genes for research related to brain functioning.

This research is useful only as a stepping stone in learning about cognitive functioning in the context of cannabis use. It is not intended to provide important genetic information about your health. We have no plan to return any research results to you or your doctor. The results of the genetic testing will not be placed in your medical record. Your taking part in this additional genetics study is voluntary, and you may decide to stop being in the study at any time or decide not to join the study. If you change your mind and want to withdraw your saliva sample from further genetic research you can do so at any time by contacting Dr. Schuster or Dr. Evins. Any information obtained from the sample will also be withdrawn except to the extent to which the information has already been used in analyses. All information and samples obtained for this study will be assigned a code number. No names or important numbers that could be used to identify you, like hospital medical record number or social security number, will be kept on samples. Only MGH study staff will keep the link between your subject number and your name on a computer protected by a personal password.

Would you like to provide a saliva sample to be used for genetic testing as described above? Please indicate your choice with your initials next to the appropriate answer.

YES: ________ NO: _________

Confidentiality and Information Storage:

All information obtained during this research project will be treated with strict confidentiality. Confidentiality will be protected to the extent permitted by the law. All information will be collected, handled, and available only to research staff. Information obtained during this research project will not be provided to officials or staff at the participating school. All completed questionnaires and electronic media will be identified by participant number only, and will not be marked with names or other identifying information. The key to the code will be kept separately on a password-protected computer. Only the researchers from our research study will have access to this identifying information. Information collected from you will be stored in a password-protected research database on a password-protected computer. This information will not become part of your medical record. Your information may be kept for several decades.

While the overall results of the research study will be shared with other people and may be published in scientific reports, your name and the fact that you were in the study will be kept confidential.

If you decide to drop out of this research study at a later time, please contact MGH study staff by phone at (617) 643-6673.

Confidentiality will be strictly enforced and is only limited in ways mandated by the law, which will be detailed below.

- Your research results will not be shared with you or entered into your school or medical record. This is because the research results cannot currently be used to guide your medical care.

- Through regular clinical interviews, questionnaires and conversations, we will monitor your mental health closely over the course of the 26 study visits and you will meet regularly with Dr. Schuster who is a clinical psychologist at Massachusetts General Hospital/Harvard Medical School. If you indicate that you are having many feelings of depression or anxiety and/or we notice an elevation in symptoms during the study, we will tell you about these results and recommend that you get follow-up from a counselor, therapist, psychologist or psychiatrist. We have carefully collected the names and phone numbers of local mental health professionals who are trusted in the community and will provide you with their contact information. All study staff will be properly trained on assessment, monitoring and intervention of mental health issues and all study staff will be prepared to discuss counseling options.

- If you indicate concern about substance use, we will provide you with resources for local treatment/support options.

- We are obligated by law to report any suspicion of child abuse, or to report any suspicion of intention to cause harm to self or others. If at any time, any of the completed questionnaires or interviews reveal any such concerning information, we will notify you of our concerns and, if necessary, contact the appropriate officials. Specifically, if you tell us that you have intent and/or a plan to harm yourself or someone else, we will call 911. Finally, if you discuss details about ongoing child abuse, we will call the Department of Child and Families.

What are the risks and possible discomforts from being in this research study?

Participation in this study has few risks. We will not share your identity with anyone outside the Partner's institutions, including school officials and staff. No record of your taking part and no results from this research study will enter medical or school records. However, we cannot guarantee confidentiality.

To protect your privacy, we put an ID number instead of names on the questionnaires, interview responses, computer games, and drug tests. The only people who can match names to ID numbers are members of our research team. No information about you will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care, or when the Partners Institutional Review Board monitors the research or consent process); or

- if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law.

What are the possible benefits from being in this research study?

Although you will not receive any direct benefits, the potential benefits to science and society are great because this study will help us better understand the effects that cannabis use and other health behaviors have on cognition.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You and your parent/guardian will be paid for taking part in this study. You can earn between $910 and $1,235 in reloadable cards based on your attendance and ability to stay abstinent from cannabis for six months which will be verified by urine drug tests. Payment will be provided at and in between visits. If you want to stop being in the study, you can stop at any time, but you will be paid only for the visits completed.

What will I have to pay for if I take part in this research study?

There is no cost to you for taking part in this study. The cost of all of the tests and procedures done for research will be paid for by study funds.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Randi Schuster, PhD is the person in charge of this research study. You can call Dr. Schuster at (617) 643-6673 Monday through Friday 9am to 5pm.

If you have questions about the scheduling of appointments or study visits, call Dr. Schuster at (617) 643-6673.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study

- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections) state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version Date: 1/13/2020

Partners HealthCare System
Research Consent Form

Parent Certificate of Confidentiality Template
Version Date: January 2018

Subject Identification

Protocol Title: Contingency Management for Six Months of Cannabis Abstinence among Adolescents

Principal Investigator: Randi Schuster, PhD

Site Principal Investigator:

Description of Subject Population: Healthy High-School Aged Adolescents with Cannabis Use

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about giving permission for your child to take part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

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If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you and your child. If you decide to give permission for your child to take part in this research study, you must sign this form to show that you want him/her to take part. We will give you a signed copy of this form to keep.

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 your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

The purpose of this research study is to learn about how a number of different variables may influence adolescents' thinking abilities. One of the goals of this study is to better understand how abstaining from cannabis for six months may affect one's emotions, behaviors, and thinking abilities.

We are asking your child to take part in this research study because he/she is a healthy, high school-aged adolescent who uses cannabis and is enrolled in a school participating in this project.

About 20 adolescents will take part in this pilot research study.

How long will my child take part in this research study?

It will take 26 visits to complete this research study, which will be conducted over approximately six months (or 24 weeks). Visits will last anywhere between 10 minutes and 2 hours.

What will happen in this research study?

Each of the 26 visits will occur at the participating school your child attends and we will schedule the visits based on your child's individual schedule. We will not remove your child from his/her academic classes and will try to arrange a schedule that is as minimally intrusive as possible (e.g., during lunch, free periods, before/after school). In rare circumstances (eg. shortage of available rooms on school campus), we may conduct study visits in a private space in the near-by public library. You will be notified in the event that a study visit will be conducted off school premises.

During these visits (ranging from approximately 10 minutes to 2 hours per visit), we will ask your child to:

- Fill out questionnaires that ask about topics such as his/her personality, mood, social group, health, and drug and alcohol use.
- Complete interviews about cannabis and other substance use as well as mood.
- Provide a urine sample to check for drug use.
    - This urine drug screen will not become part of your child's medical record.

We will ask your child to <u>stop</u> using cannabis after the first visit through the end of the last, twenty-sixth visit (total of approximately 6 months without cannabis use). We will also ask that all participants refrain from the use of illicit drugs and the consumption of alcohol on the day of every study visit.

Optional (not required) Saliva Samples for Genetic Testing: The collection of a saliva sample for genetic research is optional (not required). Your son/daughter can still take part in the main study even if you don't want him/her to take part in the genetic study. Giving a DNA sample involves filling 1-2 small plastic containers with your saliva. This will be done at your child's first visit and should take less than 10 minutes. His/her saliva sample will be labeled with a code number and not with his/her name or other identifying information. The coded sample will be sent to our lab at MGH, DNA will be removed and analyzed to help us find genes that may play a role in cognitive abilities related to cannabis use. A coded portion of your child's DNA sample will be used for whole genome analysis. Usually researchers study a few areas of your genetic code that are linked to a disease or condition. In our whole genome analysis, we will be using all or most of his/her genes for research related to brain functioning.

This research is useful only as a stepping stone in learning about cognitive functioning in the context of cannabis use. It is not intended to provide important genetic information about your child's health. We have no plan to return any research results to you or your child's doctor. The results of the genetic testing will not be placed in your child's medical record. Your consenting to your child taking part in this additional genetics study is voluntary, and you may decide to withdraw your child from the study at any time or decide not to let him/her join the study. If you change your mind and want to withdraw your child's saliva sample from further genetic research you can do so at any time by contacting Dr. Schuster or Dr. Evins. Any information obtained from the sample will also be withdrawn except to the extent to which the information has already been used in analyses. All information and samples obtained for this study will be assigned a code number. No names or important numbers that could be used to identify your child, like hospital medical record number or social security number, will be kept on samples. Only MGH study staff will keep the link between your child's subject number and his/her name on a computer protected by a personal password.

Do you allow your child to provide a saliva sample to be used for genetic testing as described above? Please indicate your choice with your initials next to the appropriate answer.

YES: ________ NO: _________

Confidentiality and Information Storage:

All information obtained during this research project will be treated with strict confidentiality. Confidentiality will be protected to the extent permitted by the law. All information will be collected, handled, and available only to research staff. Information obtained during this research project will not be provided to officials or staff at the participating school. All completed questionnaires and electronic media will be identified by participant number only, and will not be marked with names or other identifying information. The key to the code will be kept separately on a password-protected computer. Only the researchers from our research study will have access to this identifying information. Information collected from your child will be stored in a password-protected research database on a password-protected computer. This information will not become part of your child's school or medical record. Your child's information may be kept for several decades.

While the overall results of the research study will be shared with other people and may be published in scientific reports, your child's name, and the fact that he/she was in the study, as well as the name of the school he/she attends will be kept confidential.

If you decide to withdraw your child from this research study or he/she decides to drop out of this research study at a later time, please contact MGH study staff by phone at (617) 643-6673. As this study is not a study of your child's participating school, you must contact MGH study staff directly and may not contact school officials, staff, or personnel regarding the study.

Confidentiality will be strictly enforced and is only limited in ways mandated by the law, which will be detailed below.

> -Your child's research results will not be shared with you or entered into his/her school or medical record. This is because the research results cannot currently be used to guide his/her medical care. Although we will not disclose how your child responds to the study assessments, we would be happy to share with you blank copies of the various instruments so that you are aware of the questions that will be asked of your child.
>
> - Through regular clinical interviews, questionnaires and conversations with your child, we will monitor his/her mental health closely over the course of the 26 study visits and your child will meet regularly with Dr. Schuster who is a clinical psychologist at Massachusetts General Hospital/Harvard Medical School. If your child indicates that he/she is having many feelings of depression or anxiety and/or we notice an elevation in symptoms during the study, we will tell him/her about these results and recommend that he/she get follow-up from a counselor, therapist, psychologist or psychiatrist. We have carefully collected the names and phone numbers of local mental health professionals who are trusted in the community and will provide your child directly with their contact information. All study staff will be properly trained on assessment, monitoring and intervention of mental health issues and all study staff will be prepared to discuss youth counseling options. If your child agrees, we will tell you that we have concerns about his/her mood and that we recommended consultation with a mental health service provider.
>
> -If your child indicates concern about substance use, we will provide your child with resources for local treatment/support options. Additionally, we will perform urine drug tests for certain types of drugs at each of the visits. This includes prescription drugs and illegal drugs like

cannabis, cocaine, PCP, and sedatives. If your child's test results show that he/she has taken any of the drugs tested for, we will tell your child these results. If your child agrees, we will tell you the results.

-We are obligated by law to report any suspicion of child abuse, or to report any suspicion of intention to cause harm to self or others. If at any time, any of the completed questionnaires or interviews reveal any such concerning information, we will notify you of our concerns and, if necessary, contact the appropriate officials. We will inform your child that we are notifying either his/her parents and/or necessary others. Specifically, if your child tells us that he/she has intent and/or a plan to harm him/herself or someone else, we will tell you and call 911. If your child discusses details about ongoing child abuse, we will call the Department of Child and Families.

What are the risks and possible discomforts from being in this research study?

Participation in this study has few risks. We will not share your child's identity with anyone outside the Partner's institutions, including school officials and staff. No record of he/she taking part and no results from this research study will enter medical or school records. However, we cannot guarantee confidentiality.

To protect your child's privacy, we put an ID number instead of names on the questionnaires, interview responses, computer games, and drug tests. The only people who can match names to ID numbers are members of our research team. No information about your son/daughter will be disclosed to others without your written permission, except:

- if necessary to protect your child's rights or welfare (for example, if your son/daughter is injured and needs emergency care, or when the Partners Institutional Review Board monitors the research or consent process); or

- if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your child's identity. Any information that is obtained in connection with this study and that can be identified with your child will remain confidential and will be disclosed only with your permission or as required by law.

What are the possible benefits from being in this research study?

Although your son/daughter will not receive any direct benefits, the potential benefits to science and society are great because this study will help us better understand the effects that cannabis use and other health behaviors have on cognition.

Can I still get medical care for my child within Partners if my child doesn't take part in this research study, or stops taking part?

Yes. Your decision won't change the medical care your child gets within Partners now or in the future. There will be no penalty, and you won't lose any benefits your child receives now or has a right to receive.

Taking part in this research study is up to you. You can decide not to permit your child to take part. If you decide to permit your child to take part now, you can change your mind and your child can drop out later. We will tell you if we learn new information that could make you change your mind about your child taking part in this research study.

What should I do if I want my child to stop taking part in the study?

If your child takes part in this research study, and you want your child to drop out, you should tell us. We will make sure that your child stops the study safely. We will also talk to you about follow-up care for your child, if needed.

Also, it is possible that we will have to ask you to ask your child to drop out of the study before your child finishes it. If this happens, we will tell you why. We will also help arrange other care for your child, if needed.

Will my child or I be paid to take part in this research study?

You and your child will be paid for taking part in this study. He/she can earn between $910 and $1,235 in reloadable cards based on attendance and ability to stay abstinent from cannabis for six months, which will be verified by urine drug tests. Payment will be provided at and in between visits. If your child wants to stop being in the study, he/she can stop at any time, but he/she will be paid only for the visits completed.

What will I have to pay for if my child takes part in this research study?

There is no cost to you or your child for taking part in this study. The cost of all of the tests and procedures done for research will be paid for by study funds.

What happens if my child is injured as a result of taking part in this research study?

We will offer your child the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care your child gets for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or your child or give you other compensation for an injury, should one occur. However, you or your child are not giving up any of your legal rights by signing this form.

If you think your child has been injured or has experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Randi Schuster, PhD is the person in charge of this research study. You can call Dr. Schuster at (617) 643-6673 Monday through Friday 9am to 5pm.

If you have questions about the scheduling of appointments or study visits, call Dr. Schuster at (617) 643-6673.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your child's rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to give permission for your child to take part in this research study, or to continue with it, they want to know and can help.

If my child takes part in this research study, how will you protect my child's privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies your child. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about your child from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your child's identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections) state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your child's records

- Public health and safety authorities, if we learn information that could mean harm to your child or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify your child. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your child's identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your child's medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for your child. Please ask your study doctor if you have any questions about what information will be included in your child's medical record. Other researchers receiving your child's identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about your child or your child's participation in this study.

Even with these measures to protect your child's privacy, once your child's identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your child's identifiable information. Your permission to use and share your child's information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your child's name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Child's Privacy Rights

Subject Identification

You have the right **not** to sign this form that allows us to use and share your child's identifiable information for research; however, if you don't sign it, your child can't take part in this research study.

You have the right to withdraw your permission for us to use or share your child's identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, your child cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with law or maintain the reliability of the study.

You have the right to see and get a copy of your child's identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her identifiable information to be used and shared as described above.

______________________________	__________	__________
Parent(s)/Guardian for Child	Date	Time (optional)

Subject Identification

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Child:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Child, Ages 14-17	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version Date: 1/13/2020

Partners HealthCare System
Research Assent Form

Assent Template
Version Date: March 2013

Subject Identification

Protocol Title: Contingency Management for Six Months of Cannabis Abstinence among Adolescents

Principal/Overall Investigator: Randi Schuster, PhD

Site Principal Investigator:

Description of Subject Population: Healthy High-School Aged Adolescents with Cannabis Use

We are a team of doctors and researchers from Massachusetts General Hospital. We would like to learn more about how a number of different variables may influence adolescents' thinking abilities. We think this is critically important to understand now given that cannabis is becoming more easily accessible due to changing laws surrounding cannabis use for recreation and medical purposes.

To do this, we are asking you and other high school-aged students to take part in a research study. We are asking students who use cannabis to participate in this project. The results of the study will tell researchers at Massachusetts General Hospital many important pieces of information. First, it will tell us how easy it is for adolescents to stop using cannabis. Additionally, this study will help us understand how abstaining from cannabis for six months may affect one's emotions, behaviors, and thinking abilities. All information obtained by Massachusetts General Hospital research staff as part of this study is confidential. This study is not being sponsored by, does not involve, and is not being administered by the participating school you are enrolled in. School officials, personnel and staff, including staff at the participating school you are enrolled in, are not involved in this study in any capacity and all information obtained by Massachusetts General Hospital research staff as part of this study is confidential and will not be provided to the school participating in this project.

If you agree, you will be asked to participate in 26 visits over the course of approximately six months (or 24 weeks). All of the study visits will take place confidentially on your school campus and the time of the visits will be arranged based on your individual schedule. The visits will last between 10 minutes and 2 hours.

During the visits (ranging from approximately 10 minutes to 2 hours per visit), we will ask you to:

- Fill out questionnaires that ask about topics such as personality, mood, social group, health, and drug and alcohol use.
- Complete interviews about cannabis and other substance use as well as mood.
- Provide a urine sample to check for drug use.
    - This urine drug screen will not become part of your medical record.

Finally, Massachusetts General Hospital research staff will ask you to stop using cannabis after the first visit through the end of the last, twenty-sixth visit (total of approximately six months without cannabis use). You will be paid in reloadable cards both for session attendance as well as for abstinence, which we will verify with the urine drug tests. We ask that you refrain from the use of illicit drugs and the consumption of alcohol on the day of every study visit.

Optional (not required) Saliva Samples for Genetic Testing: The collection of a saliva sample for genetic research is optional (not required). You can still take part in the main study even if you don't want to take part in the genetic study. DNA is your genetic material, the material from which your genes are made. Your genes are inherited from your parents and passed on to your children. Genes can teach us about important things that influence your health. Giving a DNA sample involves filling 1-2 small plastic containers with your saliva. This will be done at your first visit and should take less than 10 minutes. Your saliva sample will be labeled with a code number and not with your name or other identifying information. The coded sample will be sent to our lab at MGH, DNA will be removed and analyzed to help us find genes that may play a role in cognitive abilities related to cannabis use. A coded portion of your DNA sample will be used for whole genome analysis. Usually researchers study a few areas of your genetic code that are linked to a disease or condition. In our whole genome analysis, we will be using all or most of your genes for research related to brain functioning.

This research is useful only as a stepping stone in learning about cognitive functioning in the context of cannabis use. It is not intended to provide important genetic information about your health. We have no plan to return any research results to you or your doctor. The results of the genetic testing will not be placed in your medical record. Your taking part in this additional genetics study is voluntary, and you may decide to stop being in the study at any time or decide not to join the study. If you change your mind and want to withdraw your saliva sample from further genetic research you can do so at any time by contacting Dr. Schuster or Dr. Evins. Any information obtained from the sample will also be withdrawn except to the extent to which the information has already been used in analyses. All information and samples obtained for this study will be assigned a code number. No names or important numbers that could be used to identify you, like hospital medical record number or social security number, will be kept on samples. Only MGH study staff will keep the link between your subject number and your name on a computer protected by a personal password.

Would you like to provide a saliva sample to be used for genetic testing as described above? Please indicate your choice with your initials next to the appropriate answer.

YES: ________ NO: _________

Two potential risks of participating in this project are that we are asking you about possibly sensitive topics (such as your moods, experiences, and cannabis use) and you may not want the personal information you provide to be shared with anyone else. To protect your privacy, we put an ID number instead of your name on the questionnaires, interview responses, computer games, and drug tests. The only people who can match your name to your ID number are members of our research team. This way, no one else -- including your parents, teachers, or other people in your school -- will be able to identify you with your responses on the questionnaire or interview. In other words, your responses are kept confidential by Massachusetts General Hospital research staff. We do this to protect your privacy and so that you can answer honestly. We will not tell anyone your responses. We would break confidentiality only in the rare event that you would need emergency care or that you would tell us specific information about a plan to hurt yourself or others. In this rare event, we would need to inform either your parents and/or another appropriate authority; however, we will tell you first before we break confidentiality. Specifically, if you tell us that you have intent and/or a plan to harm yourself or someone else, we will tell your parents and call 911. If you discuss details about ongoing child abuse, we will call the Department of Child and Families. The data that you provide to us will be kept for 10 years and then destroyed.

You will be paid for taking part in this study. You can earn between $910 and $1,235 in reloadable cards based on your attendance and ability to stay abstinent from cannabis for six months which will be verified by urine drug tests. Payment will be provided at and in between visits. If you want to stop being in the study, you can stop at any time, but you will be paid only for the visits completed.

You can choose whether to be in this study or not. If you don't want to be in this study, you don't have to participate; no one will be upset if you don't want to be involved in this project. If you volunteer to be in this study and later change your mind, you can stop and no one will be upset. You may also refuse to answer any questions you don't want to answer and still remain in the study.

You can ask any questions that you have about the study by calling Dr. Randi Schuster directly at (617) 643-6673.

Signing your name below means that you agree to be in this study. You also need parental permission before you can participate in this study. We recommend that you discuss this form with your parents before signing. They will be given a separate form to review and sign.

The information collected about you during this study will be kept safely locked up, and nobody will know who you are except the people doing the research. If we write an article about what we learn from the study, we will not use your name.

Before you decide to take part in this study, we will answer any questions you have. You can also talk to your mom or dad, or your doctor. You do not have to be in this study, it is okay to say no. If you decide to be in this study, you can change your mind and stop being part of it at any time.

You will be given a copy of this form to keep for yourself.

If you decide to be in the study, please sign your name below.

____________________________________ ____________________
Subject’s Signature Date

Assent Form Version: 1/13/2020