Cognitive Recovery With Cannabis Abstinence Among
High School-Aged Adolescents
NCT03276221
Document Date: 09/21/2023

Protocol Title: Cognition and Adolescent Health

Principal Investigator: Randi Schuster, PhD

Site Principal Investigator:

Description of Subject Population: Healthy School-Aged Children and Adolescents, Healthy School-Aged Children and 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 how a number of different variables may influence children's and adolescents' thinking abilities. One of the goals of this study is to better understand differences in cognitive capacity among children and adolescents who use cannabis and those who do not.

We are asking you to take part in this research study because you are a healthy, school-aged child or adolescent over the age of 18. We are enrolling students both who have and have not used cannabis.

About 200 children and adolescents will take part in this research study.

How long will I take part in this research study?

It will take nine visits (plus two optional scan visits) to complete this research study, which will be conducted over approximately 60 days. Visits will last anywhere between 10 minutes and 2 hours.

What will happen in this research study?

Each of the nine visits will occur at the MGH Center for Addiction Medicine and we will schedule the visits based on your individual schedule. The two optional scan visits will occur at the MGH MRI Center in the Charlestown Navy Yard.

During these visits, we will ask you to:

- Fill out questionnaires (Visits 1 through 9)
    - You will 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, moods, and family psychiatric history (Visits 1 through 9)
- Provide a urine sample to check for drug use (Visits 1 through 9)
    - This urine drug screen will not become part of your medical record
- Participate in computer tasks looking at memory, attention and decision-making (Visits 2, 5, 6, 7, 8, and 9).

If you are a cannabis user, we may ask you to stop using cannabis after the second visit through the end of visit eight (total of approximately 30 days without cannabis use). Approximately half of the cannabis users enrolled will be asked to stop using cannabis for approximately the first 30 days they are part of the study. We will also ask that all participants refrain from the use of illicit drugs and the consumption of alcohol within 24 hours 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 and initial on the line below.

YES: ____ NO: ____ Initials: _____

Optional (not required) MRI Scan Sessions: The two MRI scan sessions are optional (not required). You can still take part in the main study even if you don't want to take part in the MRI study. The MRI portion of the study will investigate possible changes in the brain and we will select a subset of participants to undergo MRI scanning. If you are selected to undergo MRI procedures and choose to participate, we will take pictures or images of your brain using a 3T MRI machine. These assessments will occur as close as possible *(within approximately two weeks)* to your baseline visit (Visit 2) and to Visit 8 at one month, depending on your schedule and availability. These images allow us to see which parts of the brain are active when you move a part of your body, such as your hand or foot, or when you speak. The MRI test will take about 1.5 hours. The MRI will be done at the MGH MRI Center in the Charlestown Navy Yard.

An MRI uses a strong magnet and radio waves to take these pictures. Since MRI uses a large magnet, people who have certain metal implants cannot have this scan. Also you will be asked to remove all metal items before the scan.

During the MRI, you will lie on a table that slides into a ring-shaped machine a little wider than your body. During the MRI, you will hear knocking, tapping and buzzing sounds made by the MRI machine. You will be wearing headphones and/or earplugs so the sounds will not be too loud. Part of the time you will be resting. Most of the time, we will ask you to perform a computer task. If at any time you feel uncomfortable and want to stop the task or the MRI, we will stop right away.

Prior to each MRI scan, we will ask you to provide a urine sample to check for pregnancy (if female) and drug use. The results of this urine screen will not become part of your medical record, and the results will not be shared with you. However, if you have a positive pregnancy test, we will share those results with you.

Would you like to take part in the MRI portion of the study if selected by our study staff? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

Optional (not required) Fitbit/ActiGraph GTX-9 Component: You can still take part in the main study even if you do not want to take part in the Fitbit/ActiGraph GTX-9 portion of the study. This portion of the study aims to measure patterns of activity and sleep over time. If you give your permission, we will provide you with a Fitbit Charge 3, Fitbit Inspire 2, ActiGraph GTX-9 to wear for the duration of the study, after which you will return the Fitbit device to our team.

The Fitbit/ActiGraph GTX-9 device will track sleep and activity across approximately 60-80 days and be worn from the time of enrollment up until the last visit of the study. If you choose to participate in this portion of the study, we will instruct you on how to charge and sync the device.

Would you like to take part in the Fitbit/ActiGraph GTX-9 portion of the study? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

<u>Confidentiality and Information Storage:</u>

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. 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 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 eight 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.

Optional (not required) Communication via Texting Service: The study utilizes a third-party service, Google Voice, which we will use to send reminder de-identified text messages asking participants to confirm their appointments the day before the scheduled appointment and to sync and charge your Fitbit/ActiGraph GTX-9 (if you consent to participate in the optional Fitbit/ActiGraph GTX-9 portion of the study). If you agree to the research staff contacting you through this service, only your telephone number will be stored in this system. If you change your mind and want to withdraw from being contacted via this service, you can do so at any time by contacting any member of the study staff.

Would you like to be contacted via this texting service as described above? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

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. No record of your taking part and no results from this research study will enter medical 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.

Risk of MRI Scans:

MRIs use powerful magnets to make images. There are no known radiation risks associated with MRI. However, persons with metal implants, such as surgical clips, or pacemakers should not have an MRI. All credit cards and other items with magnetic strips should also be kept out of the MRI room. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow tube. The MRI makes loud banging noises as it takes images. Earplugs can be used to reduce the noises. You may also experience peripheral stimulation, which may feel like a gentle tap or sensation of mild electric shock. The MRI can be stopped at any time at your request. Due to possible unknown risks to pregnant women, if there is a chance that you're pregnant we will ask you to withdraw from the study. The MRI has the potential, during normal routine use, to cause localized warming of your skin and the underlying tissues. You should immediately inform us if you experience discomfort due to warming and the procedure will be stopped.

We are doing the MRI in this study to answer research questions, not to give you medical care. The information created by this study will not usually become part of your hospital record. This MRI is not the same as one that your doctor would order. It may or may not show problems that would be found on a standard MRI. If we do see something that looks like a medical problem, we will ask a radiologist (a doctor who specializes in x-rays/scans/test results of this sort) to review the results. If the radiologist thinks there might be a problem, we will tell you and help you get follow-up care. We will only share this information with you if a radiologist thinks that you might have a medical problem, so that we don't cause you to worry needlessly.

Risk of Fitbits/ActiGraph GTX-9:

It is not anticipated that there will be any negative side effects from wearing the Fitbit Charge 3, Fitbit Inspire 2, or ActiGraph GTX-9 device. A small number of people either find the device uncomfortable or have reactions to the device or band. Should that occur, you can notify staff and either place it at another site on the body or take off the device if needed. Alternate material Fitbit/ActiGraph GTX-9 bands can be ordered as needed.

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.

You may also enjoy seeing the exercise and heart rate data that the Fitbit/ActiGraph GTX-9 displays.

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 will be paid for taking part in this study. You can earn up to $420 in vouchers and gift cards of your choice based on your group assignment, attendance, performance on cognitive tasks, and ability to stay abstinent from cannabis which will be verified by urine drug tests (if assigned to this group). If you undergo the optional MRI scans, you can earn additional payment up to $80 ($40 for each of two scans). Up to $20 in travel reimbursement ($10 for each of two scans) will also be provided for the MRI scans. If you take part in the optional Fitbit/ActiGraph GTX-9 component, you can earn up to $85, $10 for each of the six study intervals (weekly for visits 1-8, monthly for visits 8-9 based on compliance) and $25 if selected to participate in an additional 2-week study period after visit 9 (based on compliance). All payments are calculated separately and based on weekly compliance. If the device is lost or not returned, 20% of the total earned for this optional portion of the study will be deducted. 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.

A. Eden Evins, MD, MPH and Randi Schuster, PhD are the people in charge of this research study. You can call either of these doctors at (617) 643-4679 (Dr. Evins) or (617) 643-6673 (Dr. Schuster) 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 that identifies you. In the rest of this section, we refer to this information simply as "health information."

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

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

Certificate of Confidentiality for Health Information and Other Identifying Information from the Research

In this research study, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). By granting the Certificate, DHHS is not approving the research itself, but is helping us strengthen the privacy protections for your health information and other identifying information from the research. With the Certificate, we cannot be forced (for example by court order or subpoena) to disclose your health information or other identifying information from the research in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. (Note that information that is not from the research, such as existing hospital or office health records, is protected by general privacy law but does not receive the Certificate's stronger protection. The Certificate also does not prevent you or a member of your family from voluntarily releasing any information about yourself or your involvement in this research study.)

Why Health Information and Other Identifying Information from the Research Might Be Used or Shared, and By/With Whom

Even with these privacy protections, your health information and other identifying information from the research may still be used within Partners by the researchers and the staff involved in this research study, by the Partners ethics board that oversees the research, and by other staff within Partners who need the information to do their jobs (such as for treatment, payment (billing) or health care operations such as overseeing the quality of care or research). Your

information may also be shared by these groups with others outside of Partners for certain purposes as follows.

We may use and share your information with:

- The sponsor(s) of the research study, and people or groups it hires to help perform this research study
- Other researchers and medical centers that are part of this research study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do certain work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as DHHS and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), with other U.S. or foreign government bodies, and with organizations that provide independent accreditation and oversight of hospitals and research. For example, disclosure may be necessary upon request of DHHS for an audit, program evaluation, or investigation. Disclosure may also be necessary if required by the federal Food, Drug, and Cosmetic Act or its regulations.
- A public health or public safety authority, or with specific individuals who may be at risk of harm, if we learn information that could mean harm to you or others. When state mandatory reporting statutes would require us to disclose information, including about child or elder abuse, we will voluntarily disclose that information.

What Study Information May Become Part of Your Electronic Medical Record?

Information about your participation in this research study will not be included in your electronic medical record.

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information

is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain 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 health information. The protections of the Certificate of Confidentiality and other Partners privacy protections will continue to apply to your health information and other identifying information from the research for as long as our researchers keep the information.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifying 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 health 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 health 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. The Certificate of Confidentiality and other Partners privacy protections will continue to apply to your health information and other identifying information from the research that our researchers keep.

You have the right to see and get a copy of your health 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.

You have the right to see and get a copy of your health 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.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health 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: 9/20/2022

Protocol Title: Cognition and Adolescent Health

Principal Investigator: Randi Schuster, PhD

Site Principal Investigator:

Description of Subject Population: Healthy School-Aged Children and Adolescents, Healthy School-Aged Children and Adolescents with Cannabis Use

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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.

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We are asking your child to take part in this research study because he/she is a healthy, school-aged child or adolescent. We are enrolling students both who have and have not used cannabis.

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- Fill out questionnaires (Visits 1 through 9)
    - Your son/daughter will 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, moods, and family psychiatric history (Visits 1 through 9)
- Provide a urine sample to check for drug use (Visits 1 through 9)
    - This urine drug screen will not become part of your child's medical record
- Participate in computer tasks looking at memory, attention and decision-making (Visits 2, 5, 6, 7, 8, and 9).

If your son/daughter is a cannabis user, we may ask him/her to stop using cannabis after the second visit through the end of visit eight (total of approximately 30 days without cannabis use). Approximately half of the cannabis users enrolled will be asked to stop using cannabis for approximately the first 30 days they are part of the study. We will also ask that all participants refrain from the use of illicit drugs and the consumption of alcohol within 24 hours 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 and initial on the line below.

YES: ____ NO: ____ Initials: _____

Optional (not required) MRI Scan Sessions: The two MRI scan sessions are optional (not required). Your son/daughter can still take part in the main study even if they don't want to take part in the MRI study. We will select a subset of participants to undergo MRI scanning. If your son/daughter is selected to undergo MRI procedures and chooses to participate, we will take pictures or images of their brain using a 3T MRI machine. These assessments will occur as close as possible *(within approximately two weeks)* to their baseline visit (Visit 2) and to Visit 8 at one

month, depending on their schedule and availability. The MRI portion of the study will investigate possible changes in the brain. The MRI test will take about 1.5 hours. The MRI will be done at the MGH MRI Center in the Charlestown Navy Yard.

An MRI uses a strong magnet and radio waves to take these pictures. Since MRI uses a large magnet, people who have certain metal implants cannot have this scan. Also your son/daughter will be asked to remove all metal items before the scan.

During the MRI, your son/daughter will lie on a table that slides into a ring-shaped machine a little wider than your body. During the MRI, they will hear knocking, tapping and buzzing sounds made by the MRI machine. They will be wearing headphones and/or earplugs so the sounds will not be too loud. Part of the time they will be resting. Most of the time, we will ask them to perform a computer task. If at any time they feel uncomfortable and want to stop the task or the MRI, we will stop right away.

Prior to each MRI scan, we will ask your child to provide a urine sample to check for pregnancy (if female). The results of this urine screen will not become part of your child's medical record, and the results will not be shared with you. However, if your daughter has a positive pregnancy test we will inform her and encourage her to share those results with you.

Do you allow your child to take part in the MRI portion of the study if they choose to participate and if selected by our study staff? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

Optional (not required) Fitbit/ActiGraph GTX-9 Component: Your son/daughter can still take part in the main study even if they do not want to take part in the Fitbit/ActiGraph GTX-9 portion of the study. This portion of the study aims to measure patterns of activity and sleep over time. If you give your permission and your son/daughter chooses to participate, we will provide them with a Fitbit Charge 3, Fitbit Inspire 2, or ActiGraph GTX-9 to wear for the duration of the study, after which they will return the device to our team.

The Fitbit/ActiGraph GTX-9 device will track sleep and activity across approximately 60-80 days and be worn from the time of enrollment up until the last visit of the study. If your son/daughter chooses to participate in this portion of the study, we will instruct him/her on how to charge and sync the device.

Do you allow your child to take part in the Fitbit/ActiGraph GTX-9 portion of the study if they choose to participate? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

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. 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 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 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.

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, including whether or not he/she uses cannabis, will not be shared with you or entered into his/her 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 nine 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 and breath 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, the guidance counselor, and call 911. If he/she says that he/she has recurrent thoughts about harming him/herself or someone else but does not have intent or a plan to do so, we will tell you and the guidance counselor who may decide to inform you. Finally, if your child discusses details about ongoing child abuse, we will call the Department of Child and Families and will inform the guidance counselor.

Optional (not required) Communication via Texting Service: The study utilizes a third-party service, Google Voice, which we will use to send reminder de-identified text messages asking participants to confirm their appointments the day before the scheduled appointment and to sync and charge their Fitbit/ActiGraph GTX-9 (if they consent to participate in the optional Fitbit/ActiGraph GTX-9 portion of the study). If your child agrees to the research staff contacting him/her through this service, only their telephone number will be stored in this system. If they change their mind and want to withdraw from being contacted via this service, they can do so at any time by contacting any member of the study staff.

If your child would like to be contacted via this texting service as described above, they can indicate their choice with their initials next to the appropriate answer.

YES: ____ NO: ____ Initials: _____

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. No record of he/she taking part and no results from this research study will enter medical 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.

Risk of MRI Scans:

MRIs use powerful magnets to make images. There are no known radiation risks associated with MRI. However, persons with metal implants, such as surgical clips, or pacemakers should not have an MRI. All credit cards and other items with magnetic strips should also be kept out of the MRI room. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow tube. The MRI makes loud banging noises as it takes images. Earplugs can be used to reduce the noises. Your child may also experience peripheral stimulation, which may feel like a gentle tap or sensation of mild electric shock. The MRI can be stopped at any time at your child's request. Due to possible unknown risks to pregnant women, if

there is a chance that your child is pregnant we will ask them to withdraw from the study. The MRI has the potential, during normal routine use, to cause localized warming of your skin and the underlying tissues. Your child should immediately inform us if they experience discomfort due to warming and the procedure will be stopped.

We are doing the MRI in this study to answer research questions, not to give your child medical care. The information created by this study will not usually become part of your child's hospital record. This MRI is not the same as one that your child's doctor would order. It may or may not show problems that would be found on a standard MRI. If we do see something that looks like a medical problem, we will ask a radiologist (a doctor who specializes in x-rays/scans/test results of this sort) to review the results. If the radiologist thinks there might be a problem, we will tell you and your child and help them get follow-up care. We will only share this information with you if a radiologist thinks that your child might have a medical problem, so that we don't cause you and your child to worry needlessly.

Risk of Fitbits/ActiGraph GTX-9:

It is not anticipated that there will be any negative side effects from wearing the Fitbit Charge 3, Fitbit Inspire 2, or ActiGraph GTX-9 device. A small number of people either find the device uncomfortable or have reactions to the device or band. Should that occur, you or your child can notify staff and either place it at another site on the body or take off the device if needed. Alternate material Fitbit/ActiGraph GTX-9 bands can be ordered as needed.

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. When we finish the research, we hope that we will know more about the relationship between sleep and cognition in adolescents.

You may also enjoy seeing the exercise and heart rate data that the Fitbit/ActiGraph GTX-9 displays.

Can my child still get medical care within Partners if s/he doesn't take part in this research study, or if s/he 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 him/her to take part now, you can change your mind and have him/her 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 him/her 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 your child to drop out of the study before s/he 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?

Your child will be paid for taking part in this study. He/she can earn up to $420 in vouchers and gift cards of their choice based on attendance, group assignment, performance on cognitive tasks, participation in the optional MRI Scan sessions, and ability to stay abstinent from cannabis which will be verified by urine drug tests (if assigned to this group). If your child undergoes the optional MRI scans, they can earn additional payment up to $80 ($40 for each of two scans). Up to $20 in travel reimbursement ($10 for each of two scans) will also be provided for the MRI scans. If your child takes part in the optional Fitbit/ActiGraph GTX-9 component, they can earn up to $85, $10 for each of the six study intervals (weekly for visits 1-8, monthly for visits 8-9 based on compliance) and $25 if selected to participate in an additional 2-week study period after visit 9 (based on compliance). All payments are calculated separately and based on weekly compliance. If the device is lost or not returned, 20% of the total earned for this optional portion of the study will be deducted. 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.

A. Eden Evins, MD, MPH and Randi Schuster, PhD are the people in charge of this research study. You can call either of these doctors at (617) 643-4679 (Dr. Evins) or (617) 643-6673 (Dr. Schuster) 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 that identifies your child. In the rest of this section, we refer to this information simply as "health information."

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

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

Certificate of Confidentiality for Health Information and Other Identifying Information from the Research

In this research study, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). By granting the Certificate, DHHS is not approving the research itself, but is helping us strengthen the privacy protections for your child's health information and other identifying information from the research. With the Certificate, we cannot be forced (for example, by court order or subpoena) to disclose your child's health information or other identifying information from the research in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. (Note that information that is not from the research, such as existing hospital or office health records, is protected by general privacy law but does not receive the Certificate's stronger protection. The Certificate also does not prevent you or a member of your family from voluntarily releasing any information about your child or his/her involvement in this research study.)

Why Health Information and Other Identifying Information from the Research Might Be Used or Shared, and By/With Whom

Even with these privacy protections, your child's health information and other identifying information from the research may still be used within Partners by the researchers and the staff involved in this research study, by the Partners ethics board that oversees the research, and by other staff within Partners who need the information to do their jobs (such as for treatment, payment (billing) or health care operations such as overseeing the quality of care or research). Your child's information may also be shared by these groups with others outside of Partners for certain purposes as follows.

We may use and share your child's information with:

- The sponsor(s) of the research study, and people or groups it hires to help perform this research study
- Other researchers and medical centers that are part of this research study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do certain work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as DHHS and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), with other U.S. or foreign government bodies, and with organizations that provide independent accreditation and oversight of hospitals and research. For example, disclosure may be necessary upon request of DHHS for an audit, program evaluation, or investigation. Disclosure may also be necessary if required by the federal Food, Drug, and Cosmetic Act or its regulations.
- A public health or public safety authority, or with specific individuals who may be at risk of harm, if we learn information that could mean harm to your child or others. When state mandatory reporting statutes would require us to disclose information, including about child or elder abuse, we will voluntarily disclose that information.

What Study Information May Become Part of Your Child's Electronic Medical Record?

Information about your child's participation in this research study will not be included in your child's electronic medical record.

Some people or groups who get your child's health information might not have to follow the same privacy rules that we follow and might use or share your child's health information without

your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your child's health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your child's health information only when we must, and we ask anyone who receives it from us to take measures to protect your child's privacy. The sponsor has agreed that it will not contact your child without your permission and will not use or share your child's information for any mailing or marketing list. However, once your child's information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain 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 health information. The protections of the Certificate of Confidentiality and other Partners privacy protections will continue to apply to your child's health information and other identifying information from the research for as long as our researchers keep the information.

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 identifying information **will not** be used for these purposes without your specific permission.

Your Child's Privacy Rights

You have the right **not** to sign this form that allows us to use and share your child's health 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 health 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. The Certificate of Confidentiality and other Partners privacy protections will continue to apply to your child's health information and other identifying information from the research that our researchers keep.

You have the right to see and get a copy of your child's health 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 health information to be used and shared as described above.

_____	_____	_____
Parent(s)/Guardian for Child	Date	Time (optional)

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 parent(s)/guardian and child.
- 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: 9/20/2022

Protocol Title: Cognition and Adolescent Health

Principal Investigator: Randi Schuster, PhD

Site Principal Investigator:

Description of Subject Population: Healthy School-Aged Children and Adolescents, Healthy School-Aged Children and 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 how a number of different variables may influence children's and adolescents' thinking abilities. One of the goals of this study is to better understand differences in cognitive capacity among children and adolescents who use cannabis and those who do not.

We are asking you to take part in this research study because you are a healthy child or adolescent over the age of 18 who is enrolled in a school participating in this project. We are enrolling students both who have and have not used cannabis.

About 200 children and adolescents will take part in this research study.

How long will I take part in this research study?

It will take nine visits (plus two optional scan visits) to complete this research study, which will be conducted over approximately 60 days. Visits will last anywhere between 10 minutes and 2 hours.

What will happen in this research study?

Each of the nine visits will occur at the participating school which you are enrolled in 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). The two optional scan visits will occur at the MGH MRI Center in the Charlestown Navy Yard.

During these visits, we will ask you to:

- Fill out questionnaires (Visits 1 through 9)
    - You will 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, moods, and family psychiatric history (Visits 1 through 9)
- Provide a urine sample to check for drug use (Visits 1 through 9)
    - This urine drug screen will not become part of your medical record
- Participate in computer tasks looking at memory, attention and decision-making (Visits 2, 5, 6, 7, 8, and 9).

If you are a cannabis user, we may ask you to stop using cannabis after the second visit through the end of visit eight (total of approximately 30 days without cannabis use). Approximately half of the cannabis users enrolled will be asked to stop using cannabis for approximately the first 30 days they are part of the study. We will also ask that all participants refrain from the use of illicit drugs and the consumption of alcohol within 24 hours 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 and initial on the line below.

YES: ____ NO: ____ Initials: _____

Optional (not required) MRI Scan Sessions: The two MRI scan sessions are optional (not required). You can still take part in the main study even if you don't want to take part in the MRI study. The MRI portion of the study will investigate possible changes in the brain and we will select a subset of participants to undergo MRI scanning. If you are selected to undergo MRI procedures and choose to participate, we will take pictures or images of your brain using a 3T MRI machine. These assessments will occur as close as possible *(within approximately two weeks)* to your baseline visit (Visit 2) and to Visit 8 at one month, depending on your schedule and availability. These images allow us to see which parts of the brain are active when you move

a part of your body, such as your hand or foot, or when you speak. The MRI test will take about 1.5 hours. The MRI will be done at the MGH MRI Center in the Charlestown Navy Yard.

An MRI uses a strong magnet and radio waves to take these pictures. Since MRI uses a large magnet, people who have certain metal implants cannot have this scan. Also, you will be asked to remove all metal items before the scan.

During the MRI, you will lie on a table that slides into a ring-shaped machine a little wider than your body. During the MRI, you will hear knocking, tapping and buzzing sounds made by the MRI machine. You will be wearing headphones and/or earplugs so the sounds will not be too loud. Part of the time you will be resting. Most of the time, we will ask you to perform a computer task. If at any time you feel uncomfortable and want to stop the task or the MRI, we will stop right away.

Prior to each MRI scan, we will ask you to provide a urine sample to check for pregnancy (if female) and drug use. The results of this urine screen will not become part of your medical record, and the results will not be shared with you. However, if you have a positive pregnancy test, we will share those results with you.

Would you like to take part in the MRI portion of the study if selected by our study staff? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

Optional (not required) Fitbit/ActiGraph GTX-9 Component: You can still take part in the main study even if you do not want to take part in the Fitbit/ActiGraph GTX-9 portion of the study. This portion of the study aims to measure patterns of activity and sleep over time. If you give your permission, we will provide you with a Fitbit Charge 3, Fitbit Inspire 2, ActiGraph GTX-9 to wear for the duration of the study, after which you will return the Fitbit device to our team.

The Fitbit/ActiGraph GTX-9 device will track sleep and activity across approximately 60-80 days and be worn from the time of enrollment up until the last visit of the study. If you choose to participate in this portion of the study, we will instruct you on how to charge and sync the device.

Would you like to take part in the Fitbit/ActiGraph GTX-9 portion of the study? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

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. 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 eight 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.

Optional (not required) Communication via Texting Service: The study utilizes a third-party service, Google Voice, which we will use to send reminder de-identified text messages asking participants to confirm their appointments the day before the scheduled appointment and to sync and charge your Fitbit (if you consent to participate in the optional Fitbit portion of the study). If you agree to the research staff contacting you through this service, only your telephone number will be stored in this system. If you change your mind and want to withdraw from being contacted via this service, you can do so at any time by contacting any member of the study staff.

Would you like to be contacted via this texting service as described above? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

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.

Risk of MRI Scans:

MRIs use powerful magnets to make images. There are no known radiation risks associated with MRI. However, persons with metal implants, such as surgical clips, or pacemakers should not have an MRI. All credit cards and other items with magnetic strips should also be kept out of the MRI room. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow tube. The MRI makes loud banging noises as it takes images. Earplugs can be used to reduce the noises. You may also experience peripheral stimulation, which may feel like a gentle tap or sensation of mild electric shock. The MRI can be stopped at any time at your request. Due to possible unknown risks to pregnant women, if there is a chance that you're pregnant we will ask you to withdraw from the study. The MRI has the potential, during normal routine use, to cause localized warming of your skin and the underlying tissues. You should immediately inform us if you experience discomfort due to warming and the procedure will be stopped.

We are doing the MRI in this study to answer research questions, not to give you medical care. The information created by this study will not usually become part of your hospital record. This MRI is not the same as one that your doctor would order. It may or may not show problems that would be found on a standard MRI. If we do see something that looks like a medical problem, we will ask a radiologist (a doctor who specializes in x-rays/scans/test results of this sort) to review the results. If the radiologist thinks there might be a problem, we will tell you and help you get follow-up care. We will only share this information with you if a radiologist thinks that you might have a medical problem, so that we don't cause you to worry needlessly.

Risk of Fitbits/ActiGraph GTX-9:

It is not anticipated that there will be any negative side effects from wearing the Fitbit Charge 3, Fitbit Inspire 2, or ActiGraph GTX-9 device. A small number of people either find the device uncomfortable or have reactions to the device or band. Should that occur, you can notify staff and either place it at another site on the body or take off the device if needed. Alternate material Fitbit/ActiGraph GTX-9 bands can be ordered as needed.

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.

You may also enjoy seeing the exercise and heart rate data that the Fitbit/ActiGraph GTX-9 displays.

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 will be paid for taking part in this study. You can earn up to $420 in vouchers and gift cards of your choice based on your group assignment, attendance, performance on cognitive tasks, and ability to stay abstinent from cannabis which will be verified by urine drug tests (if assigned to this group). If you undergo the optional MRI scans, you can earn additional payment up to $80 ($40 for each of two scans). Up to $20 in travel reimbursement ($10 for each of two scans) will also be provided for the MRI scans. If you take part in the optional Fitbit/ActiGraph GTX-9 component, you can earn up to $85, $10 for each of the six study intervals (weekly for visits 1-8, monthly for visits 8-9 based on compliance) and $25 if selected to participate in an additional 2-week study period after visit 9 (based on compliance). All payments are calculated separately

and based on weekly compliance. If the device is lost or not returned, 20% of the total earned for this optional portion of the study will be deducted. 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.

A. Eden Evins, MD, MPH and Randi Schuster, PhD are the people in charge of this research study. You can call either of these doctors at (617) 643-4679 (Dr. Evins) or (617) 643-6673 (Dr. Schuster) 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 that identifies you. In the rest of this section, we refer to this information simply as "health information."

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

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

Certificate of Confidentiality for Health Information and Other Identifying Information from the Research

In this research study, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). By granting the Certificate, DHHS is not approving the research itself, but is helping us strengthen the privacy protections for your health information and other identifying information from the research. With the Certificate, we cannot be forced (for example by court order or subpoena) to disclose your health information or other identifying information from the research in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. (Note that information that is not from the research, such as existing hospital or office health records, is protected by general privacy law but does not receive the Certificate's stronger protection. The Certificate also does not prevent you or a member of your family from voluntarily releasing any information about yourself or your involvement in this research study.)

Why Health Information and Other Identifying Information from the Research Might Be Used or Shared, and By/With Whom

Even with these privacy protections, your health information and other identifying information from the research may still be used within Partners by the researchers and the staff involved in this research study, by the Partners ethics board that oversees the research, and by other staff within Partners who need the information to do their jobs (such as for treatment, payment (billing) or health care operations such as overseeing the quality of care or research). Your information may also be shared by these groups with others outside of Partners for certain purposes as follows.

We may use and share your information with:

- The sponsor(s) of the research study, and people or groups it hires to help perform this research study
- Other researchers and medical centers that are part of this research study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do certain work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as DHHS and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), with other U.S. or foreign government bodies, and with organizations that provide independent accreditation and oversight of hospitals and research. For example, disclosure may be necessary upon request of DHHS for an audit, program evaluation, or investigation. Disclosure may also be necessary if required by the federal Food, Drug, and Cosmetic Act or its regulations.
- A public health or public safety authority, or with specific individuals who may be at risk of harm, if we learn information that could mean harm to you or others. When state mandatory reporting statutes would require us to disclose information, including about child or elder abuse, we will voluntarily disclose that information.

Information about your participation in this research study will not be included in your electronic medical record.

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products,

and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain 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 health information. The protections of the Certificate of Confidentiality and other Partners privacy protections will continue to apply to your health information and other identifying information from the research for as long as our researchers keep the information.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifying 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 health 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 health 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. The Certificate of Confidentiality and other Partners privacy protections will continue to apply to your health information and other identifying information from the research that our researchers keep.

You have the right to see and get a copy of your health 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 health 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: 9/20/2022

Protocol Title: Cognition and Adolescent Health

Principal Investigator: Randi Schuster, PhD

Site Principal Investigator:

Description of Subject Population: Healthy School-Aged Children and Adolescents, Healthy School-Aged Children and 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.

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 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 how a number of different variables may influence children's and adolescents' thinking abilities. One of the goals of this study is to better understand differences in cognitive capacity among children and adolescents who use cannabis and those who do not.

We are asking your child to take part in this research study because he/she is a healthy child or adolescent enrolled in a school participating in this project. We are enrolling students both who have and have not used cannabis.

About 200 children and adolescents will take part in this research study.

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

It will take nine visits (plus two optional scan visits) to complete this research study, which will be conducted over approximately 60 days. Visits will last anywhere between 10 minutes and 2 hours.

What will happen in this research study?

Each of the nine 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. The two optional scan visits will occur at the MGH MRI Center in the Charlestown Navy Yard.

During these visits, we will ask your child to:

- Fill out questionnaires (Visits 1 through 9)
    - Your son/daughter will 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, moods, and family psychiatric history (Visits 1 through 9)
- Provide a urine sample to check for drug use (Visits 1 through 9)
    - This urine drug screen will not become part of your child's medical record
- Participate in computer tasks looking at memory, attention and decision-making (Visits 2, 5, 6, 7, 8, and 9).

If your son/daughter is a cannabis user, we may ask him/her to stop using cannabis after the second visit through the end of visit eight (total of approximately 30 days without cannabis use). Approximately half of the cannabis users enrolled will be asked to stop using cannabis for approximately the first 30 days they are part of the study. We will also ask that all participants refrain from the use of illicit drugs and the consumption of alcohol within 24 hours 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 and initial on the line below.

YES: ____ NO: ____ Initials: _____

Optional (not required) MRI Scan Sessions: The two MRI scan sessions are optional (not required). Your son/daughter can still take part in the main study even if they don't want to take part in the MRI study. We will select a subset of participants to undergo MRI scanning. If your son/daughter is selected to undergo MRI procedures and chooses to participate, we will take pictures or images of their brain using a 3T MRI machine. These assessments will occur as close as possible *(within approximately two weeks)* to their baseline visit (Visit 2) and to Visit 8 at one month, depending on their schedule and availability. The MRI portion of the study will investigate possible changes in the brain. The MRI test will take about 1.5 hours. The MRI will be done at the MGH MRI Center in the Charlestown Navy Yard.

An MRI uses a strong magnet and radio waves to take these pictures. Since MRI uses a large magnet, people who have certain metal implants cannot have this scan. Also your son/daughter will be asked to remove all metal items before the scan.

During the MRI, your son/daughter will lie on a table that slides into a ring-shaped machine a little wider than your body. During the MRI, they will hear knocking, tapping and buzzing sounds made by the MRI machine. They will be wearing headphones and/or earplugs so the sounds will not be too loud. Part of the time they will be resting. Most of the time, we will ask them to perform a computer task. If at any time they feel uncomfortable and want to stop the task or the MRI, we will stop right away.

Prior to each MRI scan, we will ask your child to provide a urine sample to check for pregnancy (if female). The results of this urine screen will not become part of your child's medical record, and the results will not be shared with you. However, if your daughter has a positive pregnancy test we will inform her and encourage her to share those results with you.

Do you allow your child to take part in the MRI portion of the study if they choose to participate and if selected by our study staff? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

Optional (not required) Fitbit/ActiGraph GTX-9 Component: Your son/daughter can still take part in the main study even if they do not want to take part in the Fitbit/ActiGraph GTX-9

portion of the study. This portion of the study aims to measure patterns of activity and sleep over time. If you give your permission and your son/daughter chooses to participate, we will provide them with a Fitbit Charge 3, Fitbit Inspire 2, or ActiGraph GTX-9 to wear for the duration of the study, after which they will return the device to our team.

The Fitbit/ActiGraph GTX-9 device will track sleep and activity across approximately 60-80 days and be worn from the time of enrollment up until the last visit of the study. If your son/daughter chooses to participate in this portion of the study, we will instruct him/her on how to charge and sync the device.

Do you allow your child to take part in the Fitbit/ActiGraph GTX-9 portion of the study if they choose to participate? Please indicate your choice and initial on the line below.

YES: ____ NO: ____ Initials: _____

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, 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, including whether or not he/she uses cannabis, 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 nine 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 and breath 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, the guidance counselor, and call 911. If he/she says that he/she has recurrent thoughts about harming him/herself or someone else but does not have intent or a plan to do so, we will tell you and the guidance counselor who may decide to inform you. Finally, if your child discusses details about ongoing child abuse, we will call the Department of Child and Families and will inform the guidance counselor.

Optional (not required) Communication via Texting Service: The study utilizes a third-party service, Google Voice, which we will use to send reminder de-identified text messages asking participants to confirm their appointments the day before the scheduled appointment and to sync and charge their Fitbit/ActiGraph GTX-9 (if they consent to participate in the optional Fitbit/ActiGraph GTX-9 portion of the study). If your child agrees to the research staff contacting him/her through this service, only their number will be stored in this system. If they change their mind and want to withdraw from being contacted via this service, they can do so at any time by contacting any member of the study staff.

If your child would like to be contacted via this texting service as described above, they can indicate their choice and initial below.

YES: ____ NO: ____ Initials: _____

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.

Risk of MRI Scans:

MRIs use powerful magnets to make images. There are no known radiation risks associated with MRI. However, persons with metal implants, such as surgical clips, or pacemakers should not have an MRI. All credit cards and other items with magnetic strips should also be kept out of the MRI room. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow tube. The MRI makes loud banging noises as it takes images. Earplugs can be used to reduce the noises. Your child may also experience peripheral stimulation, which may feel like a gentle tap or sensation of mild electric shock. The MRI can be stopped at any time at your child's request. Due to possible unknown risks to pregnant women, if there is a chance that your child is pregnant we will ask them to withdraw from the study. The MRI has the potential, during normal routine use, to cause localized warming of your skin and the underlying tissues. Your child should immediately inform us if they experience discomfort due to warming and the procedure will be stopped.

We are doing the MRI in this study to answer research questions, not to give your child medical care. The information created by this study will not usually become part of your child's hospital record. This MRI is not the same as one that your child's doctor would order. It may or may not show problems that would be found on a standard MRI. If we do see something that looks like a medical problem, we will ask a radiologist (a doctor who specializes in x-rays/scans/test results of this sort) to review the results. If the radiologist thinks there might be a problem, we will tell you and your child and help them get follow-up care. We will only share this information with you if a radiologist thinks that your child might have a medical problem, so that we don't cause you and your child to worry needlessly.

Risk of Fitbits/ActiGraph GTX-9:

It is not anticipated that there will be any negative side effects from wearing the Fitbit Charge 3, Fitbit Inspire 2, or ActiGraph GTX-9 device. A small number of people either find the device uncomfortable or have reactions to the device or band. Should that occur, you or your child can notify staff and either place it at another site on the body or take off the device if needed. Alternate material Fitbit/ActiGraph GTX-9 bands can be ordered as needed.

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 my child still get medical care within Partners if s/he doesn't take part in this research study, or if s/he 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 him/her to take part now, you can change your mind and have him/her 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 him/her 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 your child to drop out of the study before s/he 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?

Your child will be paid for taking part in this study. He/she can earn up to $420 based on attendance, group assignment, performance on cognitive tasks, and ability to stay abstinent from cannabis which will be verified by urine drug tests (if assigned to this group). If your child undergoes the optional MRI scans, they can earn additional payment up to $80 ($40 for each of two scans). Up to $20 in travel reimbursement ($10 for each of two scans) will also be provided for the MRI scans. If your child takes part in the optional Fitbit/ActiGraph GTX-9 component,

they can earn up to $85, $10 for each of the six study intervals (weekly for visits 1-8, monthly for visits 8-9 based on compliance) and $25 if selected to participate in an additional 2-week study period after visit 9 (based on compliance). All payments are calculated separately and based on weekly compliance. If the device is lost or not returned, 20% of the total earned for this optional portion of the study will be deducted. 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.

A. Eden Evins, MD, MPH and Randi Schuster, PhD are the people in charge of this research study. You can call either of these doctors at (617) 643-4679 (Dr. Evins) or (617) 643-6673 (Dr. Schuster) 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 that identifies your child. In the rest of this section, we refer to this information simply as "health information."

In this study, we may collect health information about your child from:
- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Certificate of Confidentiality for Health Information and Other Identifying Information from the Research

In this research study, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). By granting the Certificate, DHHS is not approving the research itself, but is helping us strengthen the privacy protections for your child's health information and other identifying information from the research. With the Certificate, we cannot

be forced (for example, by court order or subpoena) to disclose your child's health information or other identifying information from the research in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. (Note that information that is not from the research, such as existing hospital or office health records, is protected by general privacy law but does not receive the Certificate's stronger protection. The Certificate also does not prevent you or a member of your family from voluntarily releasing any information about your child or his/her involvement in this research study.)

Why Health Information and Other Identifying Information from the Research Might Be Used or Shared, and By/With Whom

Even with these privacy protections, your child's health information and other identifying information from the research may still be used within Partners by the researchers and the staff involved in this research study, by the Partners ethics board that oversees the research, and by other staff within Partners who need the information to do their jobs (such as for treatment, payment (billing) or health care operations such as overseeing the quality of care or research). Your child's information may also be shared by these groups with others outside of Partners for certain purposes as follows.

We may use and share your child's information with:

- The sponsor(s) of the research study, and people or groups it hires to help perform this research study
- Other researchers and medical centers that are part of this research study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do certain work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as DHHS and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), with other U.S. or foreign government bodies, and with organizations that provide independent accreditation and oversight of hospitals and research. For example, disclosure may be necessary upon request of DHHS for an audit, program evaluation, or investigation. Disclosure may also be necessary if required by the federal Food, Drug, and Cosmetic Act or its regulations.
- A public health or public safety authority, or with specific individuals who may be at risk of harm, if we learn information that could mean harm to your child or others. When state mandatory reporting statutes would require us to disclose information, including about child or elder abuse, we will voluntarily disclose that information.

What Study Information May Become Part of Your Child's Electronic Medical Record?

Information about your child's participation in this research study will not be included in your child's electronic medical record.

Some people or groups who get your child's health information might not have to follow the same privacy rules that we follow and might use or share your child's health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your child's health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your child's health information only when we must, and we ask anyone who receives it from us to take measures to protect your child's privacy. The sponsor has agreed that it will not contact your child without your permission and will not use or share your child's information for any mailing or marketing list. However, once your child's information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain 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 health information. The protections of the Certificate of Confidentiality and other Partners privacy protections will continue to apply to your child's health information and other identifying information from the research for as long as our researchers keep the information.

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 identifying information **will not** be used for these purposes without your specific permission.

Your Child's Privacy Rights

You have the right **not** to sign this form that allows us to use and share your child's health 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 health 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. The Certificate of Confidentiality and other Partners privacy protections will continue to apply to your child's health information and other identifying information from the research that our researchers keep.

You have the right to see and get a copy of your child's health 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 health information to be used and shared as described above.

_____	_____	_____
Parent(s)/Guardian for Child	Date	Time (optional)

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 parent(s)/guardian and child.
- 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: 9/20/2022