Title: Motivational Interviewing and Neuroimaging with Adolescents (MINA)

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OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: 11481

Research Consent Summary

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

The purpose of this study is to examine adolescent health risk behaviors (such as substance use) and how best to create interventions that effectively reduce these behaviors and their associated harms for adolescents. By asking about your thoughts, opinions, experiences, and by looking at your brain, we are hoping to learn more about how best to improve short-term and long-term health programming for adolescents like you.

The National Institutes of Health is paying for this research study. Everyone who joins this study will fill out surveys, meet with a counselor, and complete two scans of their brain (MRI). Everyone who participates will have the chance to meet with us 5 times over the course of 12 months. You will come to OHSU for the first three meetings, during which you'll fill out questionnaires, meet with a counselor, and complete scans of your brain. Each of these sessions takes about 3-4 hours each. Then, we will call you for a short phone interview and to send you a link to secure online questionnaires at 6- and 12-months from when you complete your counselor meetings. Each of those follow ups only takes about 1 hour, and does not require you to meet with us in person. You will be compensated for your time, and you can receive up to $250 (cash for the OHSU visits and gift cards for the two follow ups) if you complete all components of the study. There is a small chance of risks associated with this study, including being scanned, answering questions about health risk behaviors, including substance use, and loss of privacy. We will talk more in a minute about the steps we will take for your protection, and we ask that you let us know if you have any questions or concerns about any of these pieces. If you agree to participate, some of your data, including information about your brain and behavior collected during this study, as well as saliva samples, may be saved for future research. Samples collected during the study may be used for genetic research.

Thank you very much for your consideration of this study. Having the voices of adolescents like you is critical to learn more about how to make health programming better for other people your age.

We encourage you to talk with your family and friends before you decide to take part in this research study. If you have any questions, please feel free to stop me and ask.

OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: 11481

Research Consent and Authorization Form

TITLE:	Motivational Interviewing and Neuroimaging with Adolescents (MINA)
PRINCIPAL INVESTIGATOR:	Sarah W. Feldstein Ewing, PhD (503) 494-6182
FUNDED BY:	National Institutes of Health (NIH)
CONFLICT OF INTEREST:	None

PURPOSE:

"You" means you or your child in this consent form.

You have been invited to be in this research study because you are a youth aged 14-19. The purpose of this study is to examine adolescent health risk behaviors (such as substance use) and how best to create interventions that effectively reduce these behaviors and their associated harms for adolescents.

This study will require 5 visits (3 to OHSU, 2 by phone/internet) and will take 12 months to complete.

If you agree to participate, some of your data, including information about your brain, behavior, and genetics collected during this study, may be saved for future research. While participation is voluntary and you can stop participating at any time if you want to, agreeing to participate in this study means that you agree to participate in each of the activities that I am going to discuss.

We are asking you to provide brain, behavior, and genetic information for this study and for future banking, which is also called a repository. These samples will be stored indefinitely and disclosed in the future for research, which may include genetic research.

Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female. The samples provided by you may be analyzed in the laboratory to determine the role of genes in developing certain behaviors or traits, and this research may help inform treatments for individuals who experience difficulties with health risk behaviors.

There will be 243 youth enrolled in this study at OHSU.

PROCEDURES:
This research study has three parts. In the first part of the study, you will complete a series of questions about your background, substance use, sexual activities, attitudes and emotions, and behaviors. Next, we will ask you to meet with a member of our staff to talk about some of your current experiences, specifically, your use of alcohol and/or other substances.

We will also look at your brain using a large machine called a magnetic resonance imaging (MRI) scanner. The MRI is a giant magnet that lets us take pictures of your brain, and involves no radiation, medications, or injections. Finally, we would like to meet with you again 3, 6 and 12 months later to see how things are going for you.

During each visit to OHSU, you will be asked to complete a breathalyzer and submit a urine sample for drug screening to confirm your self-report of substance use or abstinence. If you are female, the urine sample collected at the two scan visits may also be tested for pregnancy if you would like us to do so. The results of the drug screening will not be shared with you, your parent/guardian, or any representatives of the legal system, and will not impact your involvement in the current study.

If you agree to participate, the following things will happen:

Session 1
This first part will take place in a private room at OHSU. Before you begin, we will give you a private (or *confidential)* number that will be your number for the whole study. All information that you provide will also be private (or *confidential*). What we mean by that is your information and responses will not be reported to your friends, parents, medical staff, law enforcement, or anyone else.

After we give you your confidential number, you will complete the following:

-*Baseline questionnaires:* Here, you will sit in front of a laptop computer and complete some questions that will be read to you over headphones. The questionnaires will take about 1 hour to finish, and includes questions about your alcohol use (e.g., “How many days out of the last month did you use alcohol?”, “Have you ever missed work or school because of your alcohol use?”) and other health-related behaviors (e.g., “Have you ever had sexual intercourse?”, “Have you ever been arrested?”) You are welcome to refuse to answer any questions that you do not feel comfortable answering without penalty. This means that even if you decide to not answer certain questions you can still participate in the remainder of the study.

-*Meeting with the counselor:* You will be asked to sit in a confidential room with a member of our staff to talk about some of your current experiences. This meeting will be audio-recorded, and it is possible that this meeting will be videotaped. Any audio- and/or videotapes collected will be used for research purposes only and will not be shared with anyone outside of the research study. If you are videotaped, your videotape will be destroyed when all data collection for the study ends. A member of our staff will ask you about your thoughts before and after the meeting, and you may be asked to watch the

videotape of your meeting, if applicable, and complete a questionnaire about your experience. This meeting will take approximately 1-2 hours.

-*Saliva collection:* You will be asked to provide about ½ a teaspoon of saliva for future genetic research. This involves spitting into a small plastic tube, and can be done as part of a short break during the baseline questionnaires.

Session 2:
Approximately one week after your first session, you will complete this second session in a private room at the OHSU. It will include the following:

- *Brain imaging (MRI):* You will be asked to lie flat on a table and then will be placed partway into a long donut-shaped magnet. During scanning, you will be asked to lie very still, and you will hear loud rapping and knocking noises coming from the magnet. You will be provided with headphones and/or earplugs to block out the noise. During the MRI, you will use a handheld box with buttons on it to make responses during activities, like pressing a button to rate your agreement with audio statements, or to make choices about what picture best completes a story. You will also have the opportunity to watch a small portion of a Disney Pixar movie of your choice. The amount of time you will be in the scanner for the brain imaging will be just over 1 hour.

- *Meeting with the counselor:* You will be asked to sit in a confidential room with a member of our staff to talk about some of your current experiences. This meeting will be audio-recorded. A member of our staff will ask you about your thoughts before and after the meeting. This meeting will take 1 hour.

Follow up Sessions:
Approximately three months after your first MRI and second counselor meeting, we will ask you to return to OHSU for your 3-month follow up to complete questionnaires much like the ones you completed during Session 1. Like before, these questionnaires will take about 1 hour to complete. You will also participate in a final MRI scan identical to the one completed in Session 2. For your 6- and 12-month follow up, we will ask you to complete several questionnaires (much like the ones you complete during Session 1 and 3). Answering these questionnaires will take you approximately 60 minutes. You can complete the 6- and 12-month follow ups by phone and over the internet using a secure survey site, so that you do not need to come to OHSU for those visits. If you do not have access to the internet, you can complete these follow ups in person. As long as you are within 1 hour driving time of our research office at OHSU, we will come to a location that is convenient for you (e.g., a coffee shop, OHSU, local community center) to discreetly complete questionnaires. So as not to lose track of you if you move, we will also contact you by phone between follow-ups to make sure that your contact information is still up-to-date. That way, we can be sure to get in touch with you before the next follow-up.

Summary: Each task of the study is listed below. To be in this study, you must agree to participate in each. They include:

1. Answering questions about your background, attitudes and experiences about health behavior (such as substance use);
2. Completing brain imaging (MRI);
3. Providing saliva for future research;

4. Meeting with a counselor;
5. Being contacted so we can find you for the 3, 6 and 12 month follow-ups.

Your medical record will **not** be reviewed as part of this study. Please let us know if you have any questions or concerns about completing any of these pieces of the study.

In total, you will spend approximately 12-14 hours in this study over the next 12 months.

	Session 1 (OHSU)	Session 2 (OHSU)	3 Month (OHSU)	6 Month (phone/web)	12 Month (phone/web)
fMRI		X	X		
Counselor Meeting	X	X			
Questionnaires	X	X	X	X	X
Saliva Collection	X				
Total time	3-4 hours	3-4 hours	3-4 hours	1 hour	1 hour

In the future, your brain, behavior, and genetic information may be used by the PI and collaborating research teams for other research studies. These data will be labeled as described in the **CONFIDENTIALITY** section.

During this study, recordings of your voice will be audiotaped, and you may be videotaped. However, we will not share your recordings outside of the research team. We will retain coded versions of your audiotapes indefinitely for future research presentations and publications. If you are videotaped, we will destroy your videotape after the final study participant completes his or her 12-month follow up.

- Meaning, we will record your voice during your meetings with the counselors during Session 1 and Session 2 (1 hour each), and may videotape your first counselor meeting.
- In order to protect your identity, your recordings will be labeled by a numerical ID code, which is kept completely separate from your identifying information (e.g., age, name). All identifying information will be destroyed one month after the final participant in this study completes their final 12-month follow-up, so there will be no record of you having participated in the study, and there will be no link between your recordings and your identifiable data.

If you have any questions, concerns, or complaints regarding this study now or in the future, contact PI Feldstein Ewing and the study team at (503) 494-6182.

Incidental Findings. The MRI scan is being done to answer research questions, not to examine your brain for medical reasons. This MRI scan is not a substitute for a clinical scan (the type a doctor would order). The research scan may not show problems that may be picked up by a clinical MRI scan. If we find an abnormality that appears to require urgent follow-up, we will contact you by phone to help answer questions, recommend that you make an appointment with your doctor, and help get medical care for you if you would like assistance doing so. It is possible that you could be unnecessarily worried if a problem were

suspected, but not actually found. Our research team is always available to answer any questions you may have about your scan.

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating. However, while we will contact you throughout the 12 months to stay in touch with you, you will not be contacted if the results of the study are found to have clinical relevance in the future. This is because, after your participation is complete, we will cut the link between your coded data and your identifying information. Meaning, we will no longer be able to identify which data are yours.

RISKS and DISCOMFORTS:

I will now describe the possible risks, discomforts and side effects of the procedures, including safeguards to be used for your protection. We ask that you report to the study staff any discomforts you experience while taking part in the study.

MRI is considered minimal risk. However, the scanner is a large magnet, so it could move iron-containing objects in the room during the examination. This means that loose metal objects, like coin currency or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as unremovable piercings, braces, permanent retainers, BB pellets, or certain metal surgical implants, and/or if we cannot determine whether you have metal in your body, you will not be allowed into the MRI room and cannot have an MRI. While in the scanner, you may be bothered by feelings of claustrophobia (fear of small spaces). If you feel uncomfortable (nervous or nauseous) in the MRI scanner for any reason, we ask that you inform the research staff. The MRI also makes loud ‘drum’ beating noises during the study. Headphones will be provided for your safety and comfort. There is a small chance that muscle twitches might occur during the MRI procedure. If twitches do occur, we will ask you to immediately inform the operator. You may have the scan stopped at any time. There is a speaker in the MRI scan room as well as a window that allows the operator to view you during data collection. This allows the assistants to hear and see you at all times to ensure that you are comfortable and to allow them to respond if you are uncomfortable.

No long-term adverse effects from MRI imaging are known. However, since the effect of MRI upon early development of the fetus is unknown, girls who are pregnant should not go into the scanner. If you know that you are not pregnant, then you do not need to get a pregnancy test at your scan visits. However, if you are unsure, we recommend that you get pregnancy tested at the two scan visits. The results of the pregnancy test are private, and will not be shared with medical staff, law enforcement, or youth. However, your parent/guardian may be told the results of your pregnancy test if you are younger than 15. If you are 15 or older, the pregnancy test result will be released directly to you. It will be up to you whether or not it is released to your parent/guardian. If the pregnancy test is positive, then you will have the opportunity to meet with Dr. Feldstein Ewing, or another clinical psychologist, to discuss the results. Upon request, we can facilitate a conversation with your parents or guardians about it. If the study investigator believes that you are not receiving adequate medical care for the

pregnancy, she will refer you to a place where you can get the proper care. Although you will not be able to complete the scanning visits if the pregnancy test is positive, you will still be able to participate in the follow-up visits. All participants have an option to decline further participation in the study following the MRI screen or at any point during the study.

You may become upset from answering questions about substance use or other health behaviors and talking with the member of our staff (the counselor). Some of these questions may seem very personal or embarrassing. You may refuse to answer any of the questions that you do not wish to answer. In addition, if the questions make you very upset, please let us know and you can talk with Dr. Feldstein Ewing (a licensed clinical psychologist) or we can help you find another counselor. If your answers to any of the questionnaires bring up safety concerns, such as you expressing a serious desire to hurt or kill yourself, or you mentioning current abuse of a minor (including yourself), then we may ask you to sit down with Dr. Feldstein Ewing to discuss your responses in more detail. If we are worried about your safety, then we may break confidentiality to help keep you safe. However, we would only do so if we felt as though it was absolutely necessary.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

Although we have made efforts to protect your identity, there is a small risk of loss of confidentiality associated with future storage of your data in a repository. If the results of these studies of your brain and behavior or genetic makeup were to be accidentally released, it might be possible that the information we will gather about you as part of this study could become available to an insurer or an employer, or a relative, or someone else outside the study. Even though there are certain genetic discrimination and confidentiality protections in both Oregon law and federal law, there is still a small chance that you could be harmed if a release occurred.

If you would like more information about risks and side effects, please ask me or contact the Principal Investigator (Dr. Feldstein Ewing) using the information I give you.

BENEFITS:

You may or may not personally benefit from being in this study. We expect the project to benefit you by giving you the opportunity to examine your behaviors, which may be placing you at risk, and by allowing you the opportunity to ask an expert any questions you might have on the subject. Also, by serving as a subject, you may help us learn how to benefit other people your age in the future. In other words, we expect the project to benefit all young people like you by helping us to figure out which kinds of health programs work, and for whom they work best.

ALTERNATIVES:

You might wonder what other choices you have if you decide that you do not want to be in this study. You may choose not to be in this study.

CONFIDENTIALITY:

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Here are the special precautions we are taking to achieve this:

We will immediately code your samples so that they are never identified by your name or other personal information. In other words, your data (answers to questionnaires, MRI data, audio and video recordings from your counselor meetings) will be identified with only a numerical ID code.

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

All identifying information (e.g., name, phone number) will be kept in a locked location completely separate from the data files themselves. All identifying information, along with all videotapes, will be destroyed after the final participant in this study completes their final questionnaires, so there will be no record of you having participated in the study. All coded data will be stored in a locked location completely separate from the data files themselves.

Follow up data from the internet questionnaires will be stored upon collection in the Oregon Clinical and Translational Research Institute's REDCap system, a highly secure web-based research data collection and management system, then exported through REDCap to lab databases and stored as outlined above. The REDCap servers are housed behind both the OHSU firewall and a second ACC firewall for security, and all web-based data transmissions are encrypted with industry-standard SSL methods. This means that your internet questionnaire answers are protected by multiple levels of security, both when you submit your questionnaires and when your responses are stored in our database.

To protect your privacy, nothing you tell us will be shared with anyone in the medical or legal systems, and nothing you tell us will be shared with anyone we would contact to help us find you for follow up assessments. To help us further protect your privacy, we obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers can refuse to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the FDA.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that if you talk to someone else about your involvement in this specific study, and that individual discloses that you are a participant in this study, that may limit or remove the protections offered by the Certificate of Confidentiality. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

However, if we learn about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, we will report that to the proper authorities.

In addition, anyone whose name you give us to help us find you might also tell people of your involvement in the study, though they will have no access to any of your study data and we will not tell them anything about what the study involved. Also, anyone you talk to when making a decision about whether or not to be in the study will also be able to tell others that you were thinking about being in the study.

It is important that you know that your participation in this study will have NO impact on your status in the medical or legal systems. You will not be treated any better or worse than people who do not participate in the study.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study and store in a repository to conduct future research, as applicable.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, NIH, and the funder's representatives
- The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your records.

We will not release information about you to others not listed above, unless we suspect child or elder abuse, in which case we will report this information to the appropriate authorities. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

When information is sent outside of OHSU, we are no longer in a position to control how that information is managed and protected. In this case, your information could be used and re-released without your permission.

Data from this study may be shared with other investigators for future research studies. A code number will be assigned to you, your brain and behavioral information, your genetic samples, as well as to information about you. Only the investigators and people involved in the conduct of the study will be authorized to link the code number to you. Other investigators who may receive samples of your brain, behavioral, and genetic data for research will be given only the code number which will not identify you.

We may continue to use and disclose your information as described above indefinitely.

The law provides additional confidentiality protection for certain types of information, including drug and alcohol use, diagnosis, treatment, or referral information and mental health records.

COSTS:
There will be no cost to you or your insurance company to participate in this study.

COMPENSATION:
You will receive compensation in cash for completing each OHSU component of the study, and compensation in gift cards for the two phone/internet follow ups. In other words, you will receive $30 cash after you complete Session 1, $35 cash after you complete Session 2, $40 cash after you complete the 3-month, $45 in gift cards after you complete the 6-month, and $55 in gift cards after you complete the 12-month follow-up. You, or your parent, will be provided an additional $15 cash for each of the first three sessions to offset transportation costs. So, if you complete all parts of the study, you will earn a possible total of $250. If you withdraw before completing all parts of the study, you will only be compensated for the pieces that you have completed.

LIABILITY:
If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact PI Feldstein Ewing and her study team at (503) 494-6182.

If you are injured or harmed by the study procedures, you will be treated. OHSU and NIH do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

PARTICIPATION:
This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free

(877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

PI Feldstein Ewing, Mailing Address: 3181 SW Sam Jackson Park Rd, Mail Code DC7P, Portland, OR, 97239; Email address: feldstei@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled.

If you would like to withdraw from this study, we will no longer contact you for future follow-ups. However, the brain, behavior, and genetic data that we will collect from you will not be stored with your name or any other identifier. Therefore, there will not be a way for us to identify and destroy your materials if you decide in the future that you do not wish to participate in this research.

You may be removed from the study if you become disruptive, uncooperative, threatening, or physically violent towards research staff.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:

PARTICIPANT OPTIONS

Please indicate below if you would like to be contacted by our research group about future study participation opportunities. You can still participate in this study even if you choose to not be contacted by our research group about these opportunities.

Please read the options below and **place your initials** next to your choice.

_____ I give my consent to be contacted about future research participation opportunities.

_____ I give do not give my consent to be contacted about future research participation opportunities.

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form. For youth ages 17 and under, parent/guardian consent is also required.

Consent Name Subjects 18 years and older / Parent/Guardian of Subjects ≤17 years	**Consent Signature** Subjects 18 years and older / Parent/Guardian of Subjects ≤17 years	Date
Assent Name Subjects 17 years and under	**Assent Signature** Subjects 17 years and under	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date
For Telephone Consents Where/When Consent Call Took Place	*For Telephone Consents* Person Obtaining Consent	Date