Official Title of the Study:	Prevention of Adolescent Risky Behaviors: Neural Markers of Intervention Effects
NCT Number	NCT03370393
Date of document:	December 2, 2021
Date of upload:	March 29, 2022

UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Prevention of Adolescent Risky Behaviors: Neural Markers of Intervention Effects

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STUDY LOCATION(S):
University of California at Irvine (UCI), Irvine, CA– (949-824-4559)
California Baptist University (CBU)-Affiliated Community Agencies, Riverside, CA
Other Collaborating Community Agencies & Public Places

STUDY SPONSOR(S): National Institutes of Health

In the instance of parental permission, "You" refers to "Your child

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose
The purpose of this research study is to examine the neurological changes in African-American youth after they have completed a family intervention program called Pathways for African-American Success (PAAS).

Study Procedures
Throughout the visits, you and your child will complete some questionnaires. If you and your child are randomized into the PAAS group, you will complete the PAAS program for 6 weeks and if you are randomized into the Waitlist group, you and your child will take a 6 week break from the study assessments. Your child will also complete two MRI scans before and after the PAAS program or Waitlist period.

Expected Duration
Participation will last a total of 9 hours spanned over 5 months for participants in both PAAS and Waitlist groups and an additional 9 hours spanned over 6 weeks for the PAAS group.

Risks of Participation
The more notable risks of participation include feeling uncomfortable reporting about personal information, or any discomfort for your child while he/she completes the MRI scans.
Also, should there be a breach in confidentiality of your data, there is a slight risk that your private information could be shared with individuals who are not members of the study team.

Benefits to Participants
If you and your child are in the group that receives the PAAS program (or choose to complete the program), your child may benefit from participating in the study as they may make better decisions about avoiding risky behavior, but this cannot be guaranteed.

Benefits to Others or Society
This study will help researchers learn more about how prevention programs work and it is hoped that this information will help in the improvement of such programs.

Alternative Procedures or Treatments
There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to examine the neurological changes in African-American youth after they have completed a family intervention program called Pathways for African-American Success (PAAS). You and your child are invited to participate in a research study being conducted by the University of California, Irvine. Adolescence is a time of change and upheaval, and a time when many young people engage in risky behaviors (alcohol/drug use, unprotected sex, etc.) that can lead to negative consequences. Even though children of all backgrounds engage in such risky behaviors, in our society African-American (Black) children bear a greater burden of the consequences related to such risky behaviors (such as police searches for drugs, arrests, etc.).

Through this study, we hope to learn more about how to help African-American youth resist engaging in risky behavior. We will do this by studying the changes in their brains after participating in the PAAS program, which has been shown to help reduce such behaviors in African-American youth. PAAS is a 6-week, family-based program that helps youth and parents understand each other's values and goals, and helps youth learn skills that will help them when they face challenging situations. For example, it helps youth learn skills to make better decisions about risky situations that youth sometimes experience. PAAS is delivered to youth and parents on a computer.

Participation in this study requires the voluntary participation of both you and your child. It is extremely important that your child agrees, on his or her own, to participate.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 160 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if your child is between 11 and 14 years of age, inclusive, and African-American (Black).

Exclusion Requirements
You cannot participate in this study if your child has any MRI-exclusionary criteria, such as metals or braces. A full MRI safety screening questionnaire will be reviewed with you and your child to ensure your child is safe to have an MRI scan. Youth with major medical problems, psychiatric disorders, or certain medications will not be able to participate. We will review the details with you if it is determined that your child has problems that would prevent you both from participating in the study.

HOW LONG WILL THE STUDY GO ON?
This study includes 4 visits and takes about 9 hours over a period of 2-5 months. In addition, you and your child will spend 9 hours on the computer completing the PAAS program (described below).

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...
You will need to have "screening" exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include a phone screen that you and your child need to complete before participating in the study.

During the main part of the study...
If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include...

1) **Consent:** The first step is for you to read this document and to ask as many questions about the study and your involvement in it as you need to. If you wish to participate, we will ask you to sign the last page. We will also explain the study to your child and provide a document for him/her to sign.

2) **Surveys and Health Screening:** After the consent process, we will ask you and your child to complete a number of questionnaires about a variety of information, including your child's health, other issues related to your child and your approach to parenting. Some of the questionnaires include sensitive information such as asking about risky behaviors, impulsivity, attitudes towards sex, or family history of incarceration. If your child says that s/he is thinking about or planning to hurt him or herself, then we will discuss this information with you and ask you and your child to speak to someone today to make sure that your child is safe. We'll ask your child for a urine and saliva (spit) sample. The time to do all of this (including the consent process) will be around 4 hours. [The urine will later be screened for drugs, which can affect the brain scan results. The urine results will not be reported to you or your child because the urine test is only for research purposes. The saliva sample is to measure hormones related to puberty.]

   At the end of this visit, the research team may determine that your child may not be eligible to take part in the remaining portions of the study. We will tell you and your child if this is the case. Determining eligibility for the study is a complex process involving many assessments and a team decision. Hence, we will not be able to go into the details as to why your child cannot continue in the study.

3) **Mock MRI (brain scan):** Your next session will take place at a lab at UC Irvine. At this session, we will first prepare your child for an upcoming brain scan in a magnetic resonance imaging (MRI) scanner. We do this using a "mock" scanner that looks like the real thing but isn't. We want your child to experience what it is like to have an MRI scan before having the real one. We will also train your child in a simple computer game of chance called the "Wheel of Fortune" and another game in which he/she is asked to press a button for certain cues and not press the button for other cues. Your child will play these games during the actual MRI scan. If your child finds that he/she does not like playing these games or being in the machine, his/her participation in the study can be stopped. This session will last about 30-45 minutes.

   MRI (brain) Scan. After the training, your child will complete the MRI scan. The MRI will take pictures of your child's brain while he/she is playing the computer games. This scan will last about 1.5 hours in total. To minimize tiredness, he/she will receive a break about halfway through the scan. We may ask for a second urine sample to test for drugs. The results of this test also will not be given to you or your child. After the scan, we may ask your child to come back for a re-scan if we find that the scan results show excessive movements or other problems.

   Note: Visits at baseline (including surveys, health screening, and a MRI) may be combined, or assessments may be completed at the next study visit based on participant preference, time constraints, and staff availability. Additionally, some questionnaire measures may be completed by phone, mail, or online if they are not able to be completed at a study visit.

4) **PAAS assignment:** Next, you and your child will be assigned to either 1) participate in the PAAS prevention program, or 2) wait for 18 weeks before participating in the PAAS program. Whether you will participate in PAAS program right away or wait, will be determined by a method that mimics flipping a coin (whether you have to wait or not has nothing to do with you or your child). The PAAS program was developed specifically for African-American youth and their families. It teaches families ways to help youth reach their goals and avoid risky behaviors.

   If you are assigned to receive the PAAS program right away, it will be made available to you on a laptop computer. It consists of three sessions each week, one 45-minute session for you, one 45-minute session for your child, and one 45-minute session that you will do jointly. The program takes 6 weeks to complete. So, you will each need to spend 90 minutes a week for 6 weeks to complete the PAAS program, or a total of 9 hours each.

   At PAAS sessions 2, 4, and 6 (or weeks 2, 4, and 6 if you are in the Waitlist group), you and your child will be asked to complete several questionnaires related to your child's behavior and your approach to parenting.

5) **Repeat MRI (brain) scan.** After 6 weeks, regardless of whether you and your child are in the PAAS group or Waitlist group, your child will be scheduled for another MRI scan. This will be just like the first MRI scan, including playing the video games during the scan with a break halfway through. After the scan, we may ask your child to come back for a re-scan if we find that the scan results show excessive movements or other problems.

6) **3-month follow up**: You will then go into a three-month break. Following this, we will meet with you and your child to complete another round of questionnaires. This session will be much shorter than the first one and should take about 1-2 hours. If your child says that s/he is thinking about or planning to hurt him or herself, then we will discuss this information with you and ask you and your child to speak to someone today to make sure that your child is safe. Some or all questionnaire measures may be completed by phone, mail, or online if they are not able to be completed at a study site. If you were assigned to the Waitlist group, you can go on to participate in the PAAS program.

RETURN OF RESULTS
You and your child will not be provided any clinically relevant information that may pertain to your or your child's health.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?
There are no known harms or discomforts associate with this study beyond those encountered in normal daily life. You should talk to the research team about any side effects you and/or your child experience while taking part in the study. The possible risks and/or discomforts associated with the procedures described in this study include:

Questionnaires: You or your child may feel uncomfortable answering some of the questions. If so, you don't have to answer them, but this may mean you cannot continue in the study.

Your child's urine test and saliva sample: There are no known risks for giving a urine or saliva sample.

Computer Games: There are no known physical risks. The games could cause your child to feel anxious. If your child wishes, we will stop the games, but this will also end your participation in the study.

MRI scans**:** The MRI procedure uses a powerful magnetic field to generate detailed images of the body. The magnet could move objects within your child's body that contain metal, such as implants, clips and pacemakers. Tell the doctor if your child has any metal items within his/her body.

MRI scanning is painless but your child might experience discomfort in the machine. Your child may be bothered by feelings of claustrophobia when placed inside the MRI, or by lying in one position for a long time. In addition, loud noises occur during the study when the scanner is collecting measurements. These noises are beeping and hammering sounds and may bother your child. Temporary hearing loss has been reported from this loud noise. This is why your child will be asked to wear ear plugs.

Incidental Findings: In this study, your child will have an MRI scan. This scan is for research purposes only. Further, this is not a whole body scan. The scan will be done on your child's head only. There is a risk of an unexpected finding with the scan. If there is an unexpected finding, the finding will be shared with you and your child to take to your child's primary care physician for further review. If your child does not have a primary care physician, ask the research team for a list of current UCI primary care providers.

PAAS program: There may be something in the program's material that makes you or your child uncomfortable. If that happens, you can stop and contact the study's staff for assistance.

Randomization: You will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers. There are no known risks for randomization into the PAAS program group or the Waitlist group because the PAAS program is not a standard prevention program used in clinical settings. However, there may be a delay in receiving the intervention program if you are randomized into the Waitlist group.

Confidentiality: There is a risk that your private information may be seen by others. We take a number of precautions to prevent this, including keeping your name and your child's name separate from all research information collected from you and your child. We also protect all our information in the electronic form with a password, and all paper records are kept in locked cabinets.

Psychological discomforts: Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you and your child may be upsetting or make you and your child uncomfortable. If you and/or your child do not wish to answer a question, you can skip it and go to the next question. If you and/or your child do not wish to participate you can stop.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

You will be paid the amounts below at specified time points over the course of the study. Total compensation for participation in the entire study is $725.

Steps/Tasks	Parent	Youth	Total
1st Visit	$25	$25	$50
First MRI	--	$100-$150*	$100-$150*
PAAS Program ($15 x 6 sessions)	$90	$90	$180
PAAS or Wait-list Week 2 Questionnaires	--	$10	$10
PAAS or Wait-list Week 4 Questionnaires	--	$10	$10
PAAS or Wait-list Week 6 Questionnaires	$15	$20	$35
100% PAAS Participation Bonus	$50	$50	$100
Second MRI	--	$50-$100*	$50-$100*
3-Month Follow-up	$15	$25	$40
100% Completion Bonus	$25	$25	$50
TOTAL	**$220**	**$405-$505***	**$625-$725***

Note: *For the first MRI scan, your child will get $50 for practicing in the scanner, $50 for taking brain scans in the real scanner, and additionally your child can get up to $50, depending on the amount of money she/he earns while playing the video games. For the second MRI scan, your child will get $50 for taking brain scans, and additionally can get up to $50, depending on the amount of money she/he earns while playing the video games.

If you or your child withdraw from the study before completing all the assessments for any particular visit, there will be no payment for that visit. However, if the researcher decides to withdraw you or your child from a visit, you and/or your child will be paid for that visit even if all of the assessments are not completed.

If your child is asked to return for a separate rescan visit (due to motion artifacts, data recording error, etc.), your child will receive up to an additional $100 ($50 for the scan and $50 for earnings while playing the video games).

If you and your child complete all assessments throughout the study, your child will receive a prize (such as a toy, water bottle, socks, etc.) at the end of the study. Your child will also receive a small token during the 3-month break.

You and your child may be compensated in cash or a money order, if necessary.

Reimbursement

You will be refunded for the following expenses that you incur. We will reimburse you for your mileage at a rate of 40 cents ($0.40) per mile or bus costs for each trip you make for scheduled appointments at our lab/offices or the MRI lab up to a maximum of $40. The payment will be rounded off to the nearest dollar. If the calculation is $0.50 and under, the payment will be rounded to the previous dollar. If the calculation is $0.51 and over, the payment will be rounded up to the next dollar. For example, if the payment is $9.50, it will be rounded to $9.00. If the payment is $9.51, it will be rounded to $10.00. We will also reimburse you for parking during the two MRI visits. Please save your parking receipts. We can only reimburse you if you give us the receipts.

In the special instances where you cannot drive, do not have personal transportation, or cannot take the bus, we may provide you with taxi transportation.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?
There is no cost to you or your child for participating in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor NIH, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you if you are interested in continuing long-term follow up procedures.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

You are free to withdraw your consent to use your identifiable private information and biospecimen for future research at any time however there are some limitations. If you withdraw your consent, the researchers will not use your information or biospecimens in future research studies. However, any of your information or biospecimens already being used in a research study that began before your request to withdraw will continue to be used for that specific study. Also if information and biospecimens have already been provided to another researcher, institution, or company, it may not be possible to limit their continued and new uses.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data
Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. This is to ensure that we can contact you if there is anything of concern.

Data Storage
Research data will be stored electronically on a secure network server in an encrypted file with password protection.

Data Retention
The researchers intend to store your research data and/or de-identifiable biospecimens in a repository indefinitely. The researchers may continue to use and share your information and information obtained from analyses of your biospecimens indefinitely. Also the use and sharing of your de-identifiable biospecimens will continue until the specimens are gone.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, the study sponsor, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Future Research Use
Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

ClinicalTrials.gov
ClinicalTrials.gov is a Web site that provides information about clinical trials. 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.

Certificate of Confidentiality
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Researchers will voluntarily disclose information to prevent serious harm to you or to someone else including, suspected child abuse and neglect, or concern that you and your child may hurt yourselves or others.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Use of Biospecimens
Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

Investigator Financial Conflict of Interest
No one on the study team has a disclosable financial interest related to this research project.

Future Contact
The study team would like your permission to contact you for future research. We would like to share your data with our other studies that you may qualify or be eligible for and/or agree to participate in. Sharing your data with our other studies is entirely voluntary and optional. You will still be able to participate in our study without having to agree to future contact from other studies or to share data with those studies.

If you are interested, then we will share some of your and your child's identifiable information with other researchers at UC Irvine who may be performing similar research so that they may check your information against their eligibility criteria. If you and your child are a good match, then they may contact you to tell you more about their research. Also, if they have the same assessments, they will use the collected information so that you and your child don't have to repeat the same assessments. These researchers will follow the rules for keeping your (your child's) information private, and you can refuse to participate in these studies without any penalties.

Please initial your level of permission below.

_____ **Yes,** UCI researchers may contact me and my child in the future to ask me to take part in other research studies, and share data with other researchers.

_____ **No,** UCI researchers may **not** contact me and my child in the future to ask me to take part in other research studies and share our data with other researchers.

Supplemental/Optional Participation in Follow-up Study
In addition to the current study, we are conducting a five-year follow-up of our participants, which will only include some follow-up questionnaires that participants complete at the first visit and will provide additional compensation. Your decision is completely voluntary and will not affect your participation in the current study. If you are interested in participating in the follow-up study, please mark your answer below and you will be provided with another consent form describing the details of the follow-up study. You can check "YES" now but can choose to drop out of the study at any time and are not required to complete all follow ups.

Please initial your level of interest below

_____ **Yes,** I am interested in participating in the Supplemental Follow-up Study.

_____ **No,** I am **not** interested in participating in the Supplemental Follow-up Study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact the UCI Institutional Review Board by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep.
Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

_____
Name of Child

_____ _____
Subject (Participating Adult) Signature **Date**

_____
Printed Name of (Participating Adult) Subject

_____ _____
Legally Authorized Representative/Guardian Signature ***Date***

_____ _____
Printed Name of Legally Authorized Representative/Guardian ***Relationship to Subject***

_____ _____
Signature of Person Obtaining Informed Consent **Date**

_____
Printed Name of Person Obtaining Informed Consent

A witness signature is required on this consent form only if: ***(Researchers: check which one applies)***

IMPORTANT! If no witness signature is required, this witness signature section of the consent form may be left blank.

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

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

_____ _____
Witness Signature **Date**
Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

University of California Irvine Health
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy): Prevention of Adolescent Risky Behaviors: Neural Markers of Intervention Effects

Principal Investigator Name: Uma Rao, M.D.

Sponsor/Funding Agency (if funded): National Institutes of Health

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that health care providers can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UC Irvine Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☐ Entire Medical Record

☐ Ambulatory Clinic Records

☐ Progress Notes

☐ Other Test Reports

☐ Other (describe):

(Description of Other Health Information)

☐ Lab & Pathology Reports

☐ Dental Records

☐ Operative Reports

☐ Discharge Summary

☐ Consultations

☐ Emergency Department Records

☐ Financial Records

☐ Imaging Reports

☐ History & Physical Exams

☐ Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

_____I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____I agree to the release of HIV/AIDS testing information.

_____I agree to the release of genetic testing information.

_____I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives, or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;

4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____
Subject's Name (print)—*required*

_____ _____
Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____ _____
Parent or Legally Authorized Representative's Name (print) Relationship to Subject

_____ _____
Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____
Witness' Name (print)

_____ _____
Witness' Signature Date