University of California, Los Angeles

RISE-Up Early Adulthood + (RISE-Up EA+) Consent to Participate in Research

Introduction

You are invited to take part in a National Institutes of Health (NIH) funded research study led by Dr. Bridget Callaghan and Dr. Jennifer Silvers and other researchers including Dr. Mitchell Wong, at the University of California, Los Angeles (UCLA). You are being invited to be a participant because of your current participation in the RISE-Up Early Adulthood (RISE-Up EA) Study. You can think of our study, RISE-Up EA+, as a voluntary add-on to your participation in RISE-Up EA.

Why is this add-on study being done?

The add-on study is designed to understand the impact of early schooling experiences on individuals' health.

What will happen if you take part in this add-on research study?

If you choose to participate in this add-on study, you will attend a one-time in-person session that will take approximately 3-4 hours at UCLA. The researchers will request you to do the following:

- Complete questionnaires: Additional questionnaires, outside what was administered by RISE-Up EA, will ask questions about yourself, such as early adversity, discrimination experiences, emotion regulation strategies, health (mental/physical), stress, medications, illnesses, and sample quality.

- Complete a Magnetic Resonance Imaging (MRI) scan: During the scan, we will take images of your brain while you engage in various scanner tasks, this could include playing a variety of games and watching a movie clip. Some tasks are designed to be fun (e.g., navigating a map to find prizes), while others are designed to be relaxing (e.g., resting with your eyes closed).

  Because we are not permitted to scan pregnant women, if you inform us or indicate on the MRI screening form that you may be, or are pregnant, we will not proceed with the scan.

- Provide biological samples: After the scan, research staff will provide you with a saliva collection kit and buccal swab kit. A blood sample may be requested if it was not yet collected or sample quality was insufficient in RISE-Up EA. The blood collection method and amount will be identical to what is administered in RISE-Up EA. You will also be provided with a stool sample collection kit either before or after your in-person study visit. You will be asked to collect a pea-sized amount of stool and store the sample in a provided container and opaque bag. The completed sample will then be brought to the in-person session or mailed to our study team.

- Complete various tasks: You will engage in both fun and relaxing tasks inside of the scanner. In addition, task trainings and additional cognitive tasks will be administered outside of the scanner.

To ensure scoring accuracy, a few of the cognitive tasks administered by the researcher will be audio recorded. Such digital files will be de-identified and stored on a secure password-protected device.

Are there any potential risks or discomforts that I can expect from this study?

- Questionnaires: There is a small risk of discomfort due to answering questions about emotions and stress that may be distressing. You may choose to not respond to the questions that make you too uncomfortable. All responses will be kept private and confidential.

- MRI scan: The MRI scanning procedure requires participants to be in a small, partially enclosed space. The sound of the MRI scanner can be loud, but we will reduce the noise by providing headphones and earplugs. Tasks may be experienced as boring or difficult. Additionally, the powerful magnetism of the MRI scanner attracts certain metals, hence, individuals with metals in their body (for instance, individuals with pacemakers, infusion pumps, aneurysm clips, metal prostheses, joints, rods, or plates) will be excluded from participating. Metals in dental fillings are less susceptible to magnetism and are therefore allowed. We will thoroughly assess for the presence of metal in or on your body in the following ways: (1) we will administer an MRI screening form that goes through a list of the metals that are and are not allowed in the scanner to see if you have any of these, (2) removing all removable metal from the body before scanning (including jewelry and metal in clothes), (3) using a hand held metal detection wand on you before entering the MRI suite.

  There are no known adverse effects resulting from MRI exposure or the scanning procedure. The MRI scanner used for this research is approved by the FDA. Although research has shown that exposure to the MRI scanner has no known risks to humans and non-human animals, the risks to a fetus are currently unknown. Therefore, we ask that if you know that you are pregnant, you should not participate in the MRI scan.

  If a problem is uncovered during an MRI scan, you will receive a referral for further evaluation and/or treatment. However, we would like to point out that the type of MRI scans we are doing are optimized for research, not for detecting abnormalities. Thus, if you have a clinical concern and are looking for an MRI scan to assess for that, you should seek the help of a professional.

- Biological sample collection: There is a small risk of discomfort, including potential embarrassment, when collecting the requested biological samples. To mitigate this, we will provide participants with the appropriate kits to collect their sample, and grant privacy to make the collection. The saliva and buccal cell sample will be collected on-site, and participants will be given access to a private space to collect the sample. For the stool sample, participants will complete the sample collection in their home, and their completed sample will either be brought to their in-person study visit or mailed to our study team. For the blood sample, you may experience slight pain or bruising at the site on your arm where the needle is inserted. There is also a minimal risk of infection at the puncture site. In rare cases, the needle stick may cause fainting. We will minimize these risks as much as possible by following proper

cleaning procedures and ensuring you are well-hydrated. Additionally, participants will have the option to skip a procedure if they prefer.

Are there any potential benefits to my participation?
You will not directly benefit from your participation in this research. The results of the research may help us understand how health is impacted by education.

Will I be paid for participating?
For your participation in the MRI scan, you will receive a $75 gift card and a video of your brain. For completing a Reward task or Faces task, you will receive up to an additional $25 gift card. For completed surveys in this add-on study, not covered in RISE Up-EA, you will receive a total of $20. Additionally, you will receive $25 for completing the Vioscreen dietary screener, $25 for completing the stool sample kit, and $25 for completing the saliva and buccal cell samples. For your travel needs to UCLA for the MRI scan, you will also receive a $17 cash allowance.

How will my information be kept confidential?
Information about you is protected by a Federal Certificate of Confidentiality. Meaning, we cannot be forced to release information about you for any legal proceeding, even if a court of law asks.

Additionally, the Certificate allows us to use information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect the information shared with them.

There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).
- A federal agency audits or evaluates research that it funds.
- Researchers are required to report possible intent to harm yourself or others, child abuse, elder abuse, or infectious disease cases.
- The Food & Drug Administration requires information as part of overseeing drugs, devices or other products.

Confidentiality will be maintained by means of:

- Any information that is collected as part of this study and that identifies you will remain private and confidential. We will use a study ID number when collecting and analyzing the questionnaires, biospecimen samples, audio recordings, and your MRI scan. Only the researchers conducting this study will have the information that matches the code to any identifying information, such as your name, address, or phone number. The information that matches the code to your identifying information will be kept in a password-protected secure server. Only very few authorized people, who have specifically agreed to protect your identity, will have access to this database. All other researchers and personnel, including those who will be working with your samples, will not have access to any of this identifying information.

- All information from the study will be kept either in encrypted, password-protected files or in a locked office that only Dr. Jennifer Silvers and Dr. Bridget Callaghan have access to.

While we will not be asking about these topics, if you mention that you intend to harm someone or yourself, we are required to share this information to people who can help you. For example:

- Under California law, we will not keep information about child abuse or elder abuse confidential. If any member of the research staff is given such information, he or she is required to report it to the authorities.
- The research team may not be able to keep confidential thoughts about harming oneself. If you tell the research staff that you are thinking about killing yourself, the research staff will ask more questions about the thoughts. Depending on how strong the thoughts are or how much you feel like hurting yourself, the research staff may give you information for treatment, work with you to find a doctor, trusted family member, or therapist to discuss the thoughts. The research staff may also work with you on a plan that may include getting you to a hospital for safety.

While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, or telephone number, individuals may develop ways in the future that would allow someone to link your genetic information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Any specimens (e.g., saliva, buccal cells, stool, blood) obtained for the purposes of this study will become the property of the University of California. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any monetary compensation or other benefits derived from any commercial or other products that may be developed from use of the specimens.

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.

The researchers intend to keep the research data and records in a repository indefinitely. Other researchers will have access to the data for future research.

It is possible that other investigators conducting other research might request that data collected for this study be shared for further research. For example, investigators associated with the government agency supporting this study might make this request. Even if you agree that your data may be shared with other investigators, your name or other personal identifying information would not be revealed. Though your privacy is very important to us and we will use many safety measures to protect your privacy, it is possible that there may be unforeseen privacy risks. For example, although we would not put any personal identifying information about you in a shared database, someone in the future might find some way to link your medical information or other information collected for this study back to you even in the absence of your name or other personal identifying information. Alternatively, there could be violations to the security of the separate computer systems used to store the codes linking your information to you.

Use of data and specimens for future research
Your data and/or specimens, including de-identified data and/or specimens may be kept for use in future research.

What are my rights if I take part in this study?

- You can choose whether you want to be a part of this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision is made, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that make you too uncomfortable and remain in the study.
- You may refuse to provide a biospecimen sample or complete a particular task and remain in the study.
- You may refuse to be audio recorded and remain in the study.
- You may refuse to share your data beyond the initial investigators.
- You may refuse for your data to be used for commercial purposes.
- You may request that your data be restricted to specific types of research activities.

Who can I contact if I have questions about this study?

- **The research team:** If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

  Dr. Bridget Callaghan
  502 Portola Plaza, Room 5550
  Los Angeles, CA 90024
  Phone: (310) 794-9107
  Email: bcallaghan@ucla.edu

  Dr. Jennifer Silvers
  502 Portola Plaza, Room 2243D
  Los Angeles, CA 90024
  Phone: (310) 794-4953
  Email: silvers@ucla.edu

- **UCLA Office of the Human Research Protection Program (OHRPP):** If you have questions about your rights as a research participant, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

You will receive a copy of this consent form and the Research Participant's Bill of Rights to keep for your records.

CONSENT FOR STUDY PARTICIPATION

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date