University of Colorado Boulder

Adult Participant: Consent to Act as a Research Subject

The Adolescent Brain Cognitive Development (ABCD) Study: CU Boulder

Why is this study being done and why are you being asked to participate?

Dr. Marie Banich, Dr. Naomi Friedman, and the Adolescent Brain Cognitive Development (ABCD) investigators are conducting a research study sponsored by the National Institutes of Health to learn more about developing cognitive, social, and emotional functions in children as they grow from age 9 to young adulthood. You first joined the study as a 9- or 10-year-old when we asked both for your assent as well as your parent or caregiver's permission for you to participate. As an adult, we are inviting you to continue your participation. This same research study is being done at many other research programs across the U.S. This is one of the largest studies of its kind to date, with approximately 12,000 healthy participants across all locations. There are approximately 550 participants from Colorado.

The purpose of the study is to gain a better understanding of mental, social, emotional, and physical development during this important stage of early life, and to learn more about why children, adolescents, and young adults differ in their development. The researchers will try to determine how brain development, genetic factors, mental and physical health, education, peer and family relationships, activities and behaviors, and environmental exposure all influence young people as they mature. They will try to identify which factors seem to promote better outcomes, including emotional well-being, and factors that may increase a person's risk for a negative outcome, such as unhealthy habits like drug and alcohol use. The results of this study may help in designing new interventions that prevent negative and increase positive outcomes in young people's lives. You were asked to participate in this study because you were a 9- or 10-year-old at the beginning of the study. Several participants will also be asked to participate in the study on occasion to help us test out and evaluate the procedures and to give the researchers feedback about their experiences participating in the study. You may be one of these participants.

What are the study procedures?

Earlier in the study you completed a "baseline" assessment and have been invited to annual assessments since then. If you agree to continue your participation, you will continue to be asked to complete a set of annual assessments as well as interim additional assessments between the larger annual assessments:

<u>Clinical Interview, Cognitive Assessments, and Questionnaires</u>

- We may ask you to provide information about you and your family including your phone number, address, email, and contact information of relatives or friends. Contact information will only be used to help find you for the follow-up visits. Relatives and friends are told only that this is a study of brain and cognitive development and no other information about the study or about you or your family is given.
- We will administer questionnaires about your thoughts, behavior, personality, family, physical development, relationships with friends and family, as well as other activities. We may ask questions about school, jobs, romantic relationships and sexuality. We may also ask you questions about events you may have experienced, including some which may have been traumatic, for example, witnessing crimes, violence, or abuse, and if you were personally affected by such events. As with other questions, you do not have to answer these questions

if you would rather not answer them, and we will keep all answers confidential, except in cases where we learn a child or elder had been or is being abused.

- You will be asked to do cognitive assessments on a computer including measures of memory, language, attention, motor function, problem solving, visual spatial function, and decision making. Study staff may make observations and/or ratings of your behavior during these assessments.
- You will be asked to complete an in-person clinical interview. We will ask you about your mood and feelings, and about friends and family. We will also ask about alcohol, tobacco, caffeine, and other drugs you may know about, have used, or know someone who used.
- We might ask questions about your health over the past year, including questions about whether you have been diagnosed with or treated for any illnesses, have had any sexually transmitted infections (STIs), or have been hospitalized.
- You do not have to answer questions that make you uncomfortable. We normally will not share any information you tell us, as this helps to keep the privacy and trust needed so we get honest answers. However, if our tests suggest you may have a life-threatening medical or mental health disorder, the investigators will recommend that you receive a clinical evaluation, and you will be provided with information about local medical facilities and other resources.
- In addition to interviewing you, we may also interview your parent or other adult family member you may designate. We may ask them questions about things like your family background, behaviors, mental and physical health, and alcohol and other drug use in the family.

Brain MRI Session

- You will be asked to complete magnetic resonance imaging (MRI) of your head. The MRI will be scheduled at the Center for Innovation and Creativity on the University of Colorado Boulder campus. We will give you directions and free parking. We will do the MRI every other year.
- If you get anxious in an MRI scanner, you can have the option of doing a mock scan before the real MRI. The mock scanner looks and sounds like a real MRI .
- Because MRI involves being placed in a strong magnetic field, it is not safe to be in or near an MRI scanner if you have an implanted metal device such as a pacemaker or cochlear implant. To make sure it is safe for you we will conduct a safety screening before we schedule the MRI and again before going into the scanner.
- Pictures of your brain will be collected using an MRI scanner. For this, you will be placed in a large donut-like MRI machine for up to 90-120 minutes in total and this may be done in one or two sessions. You will be asked to hold still while we conduct the scan. We will put a cuff on one finger to measure heart rate and a band around your abdomen to measure breathing rate. The MRI technician will position you in the scanner, provide hearing protection, ensure you can view the display screen, and give you the response button box.
- In the MRI, you will either do mental tasks or just rest quietly while we image the brain. While in the scanner, some of the time you may be shown a movie, and for some of the time, you will be instructed to look at pictures, a blank screen, or press a button to complete tasks.

Vital Signs

- You will be asked to wear a cuff around one of your arms while your blood pressure is measured using an automatic electronic blood pressure monitor. We'll be measuring how this

changes over time as young people develop, as this can be an indicator of health risk. The monitor will measure your blood pressure several times in a row in brief intervals to get an accurate measurement.

Biological Samples

- We will ask you for saliva samples to study your DNA (the genetic material inside cells) or to study your hormones (chemicals in the body). To collect saliva, you will be asked to drool into small tubes. We will send these de-identified saliva samples to the RUCDR Biorepository, Salimetrics, or other companies for processing and future use. If there is not enough saliva for the analyses we may ask you to try this at home and mail the sample to us in a prepaid package.
- Depending on the visit, we may ask to draw blood. We will ask to collect blood every 1-2 years. This is voluntary but having blood will provide better genetic information for analysis as well as other markers of health (e.g., cholesterol, glucose, iron levels, and blood count measures of overall health). If you agree, a trained staff member will draw a small amount of blood. The blood sample that you provide will be used for genetic research, such as to study how genes influence brain differences and behavior, and for research on physical health. The blood will be analyzed or stored for future use labeled with codes that do not identify participants.
- As a courtesy to you, if you participate in the blood draw and/or blood pressure measurement protocols, we will send you a report with the following values once they are processed: 1) blood pressure; 2) total & HDL cholesterol; and 3) blood glucose levels (A1C). We will provide this to all participants regardless of the values. These are not provided for clinical or diagnostic purposes, but simply for your information, and you may wish to share them with your health care provider.

Please indicate whether you agree to have blood drawn:

Yes, I am willing to give blood ____

No, I do not want to give blood ____

I am not being asked to give blood at this visit ____

Sometimes genetic tests are performed to identify changes in genes associated with medical conditions, so that a patient or their doctor can use this information. This kind of medical test will not be performed. If you are interested in having this kind of medical genetic testing, you should consult your doctor. Some commercial tests are also available for this kind of testing.

- You may be asked to provide a sample of about 100 strands of hair to test for substance use and hormone developmental markers. The hairs are cut from a hidden area on the back of the head to affect your hairstyle as little as possible. Hair may be used to study exposure to environmental substances, including cigarette smoke, toxins, or drugs of abuse.
- We may ask you to give us some of your shed baby teeth if you have them. The teeth will be stored for future studies, for example, exposure to harmful things in the environment.
- Female participants may be asked to provide a urine sample for a pregnancy test prior to the MRI and pregnant participants will not be scanned. The study personnel will make sure this sample is properly discarded.

- You may be asked to provide a breath sample to test for recent alcohol use and a saliva or urine sample to test for recent drug or nicotine use. If the test shows you may be under the influence of alcohol or a drug, you won't be studied that day and we will reschedule.

Both saliva and blood are processed to extract DNA molecules, and in modern genotyping analyses, DNA is examined at many different locations across the genome. The variance that is found in each person's DNA is coded for future analysis. These and other donated samples and health information will be stored as described above.

Scientists and researchers from around the world will be able to use the information we collect for many kinds of health research. Like other data you provide throughout the study that are shared, the samples will be labeled with a unique participant code that does not identify you. Researchers must agree to an ethical code of conduct, which prohibits any attempt to identify individuals from the samples. The code of conduct also prohibits the creation of immortalized cell lines. Immortalized cell lines are cells that have been modified in a lab to keep dividing and growing indefinitely. While we do not yet know all the ways your samples may be used, we do know they will not be used to create immortalized cell lines.

Activity Tracking (Fitbit)

If you have a smart phone we may ask you to wear a Fitbit activity tracker at your visit. You must agree to Fitbit's rules before you can use it, just like you would if you bought a Fitbit for yourself. You can usually find these rules in the "Terms of Service" or the "End User License Agreement." ABCD does not control these rules. Please read them carefully. These rules may ask you to agree to certain things, like not to sue the company if something goes wrong with the device. These rules may also allow the company to get, keep, or give others a copy of your information that comes from the device. Participating in the Fitbit part of ABCD does not require any identifiable information to be shared with Fitbit, but changing settings in the Fitbit app could result in identifiable information being collected and/or shared with Fitbit. We advise you not to change any settings in the Fitbit app. For the Fitbit to accurately track your activity, we must tell Fitbit your sex, height, weight, and handedness (left or right handed). We do not give Fitbit your name or any other information about you.

We will show you how to use it and ask that you wear the tracker for three weeks. We will measure heart rate, physical activity, and sleep during this time, to be compared to other data in the study. There is a small risk of skin irritation if you have an allergy to any of the components of the Fitbit. If you notice irritation or redness, please remove the device and contact us. At the end of 3 weeks, you will be asked to return the Fitbit in a prepaid envelope, and you may be asked to answer some questions online.

Although ABCD will protect the copy of your information that you give us, we cannot protect or control what the company does with the copy that goes to them. If you do not agree to Fitbit's rules, you do not have to accept the Fitbit. You can say no and still participate in the other parts of ABCD.

Please indicate whether you agree to wear a Fitbit for the study:

Yes, I will wear a Fitbit ____

No, I do not want to wear a Fitbit ____

I am not being asked to wear a Fitbit at this visit ____

Passive Assessment of Mobile Device Usage

At the study visit, we may ask if you are willing to have applications installed onto your mobile device to monitor your mobile device use habits. If you agree to participate in this component, you will be asked to:

- Let study staff install one or more applications on your mobile device and agree to the terms of use of the app(s).

Data from the devices will be encrypted and stored on a secure Cloud server by the applications; no personally identifiable data, nor any content of any kind, will be recorded from these applications. Similarly, no details of application or website usage will be recorded except for what application is being used, when, and for how long. We also may collect information on how many key presses or words are typed, though we will not collect any of the content.

There may be costs related to this component in the form of fees from your phone carrier related to data usage depending on your phone plan.

At the end of 3 weeks, you will be asked to uninstall the application(s) from your device, and complete online questionnaires.

Please indicate whether you agree to participate in this Mobile Device component:

Yes, I will participate in the Mobile Device component ____

No, I do not want to participate in the Mobile Device component ____

I am not being asked to participate at this time ____

School Records

- We may ask for your permission to release your student records including attendance, grades, and standardized test scores as data for this study.

Teacher Questionnaire

- If you are in school, we may ask you for your primary teacher's name and permission to contact them to fill out a questionnaire about your behavior and emotions in the classroom as part of the study.

Follow-up

- About every 6 months after completing each annual assessment, we may contact you for a brief (15 minute) interview including questions on the phone and/or computer about health, school, jobs, recreational activities, relationships, experience with substance use, and current contact information.
- About every 12 months after completing each annual assessment, we will ask you to participate in the next annual assessment, which will include interviews, questionnaires, biological samples, MRI, and cognitive testing.

How much time will each study procedure take, what is your total time commitment at each follow-up, and how long will the study last?

It will take you about 6-7 hours to complete the biennial (every 2 years) assessments that include the MRI. In the annual visits between those MRI visits, we will invite you to return for some of the same assessments except the MRI, and those annual visits will take about 3-4

hours to complete. In addition, the brief interviews every 6 months will take up to 45 minutes total each year. The study is expected to go on for 10 years but could be extended beyond that.

You can do the annual study visits in one day with a meal and breaks, or we can schedule the study sessions on different days. Your appointments will be scheduled outside of school/work hours if possible, including during evenings, weekends, and holidays. We may be able to provide transportation. Some of the questionnaires may be able to be done online in advance of your visit.

How will my confidentiality and privacy be protected? Will other people have access to my data and biological samples?

Research records will be kept confidential. This means that what you tell us is not shared with your school, work, family, or friends. Your records with your name and contact information will be stored separately from data collected from you in locked cabinets or a secure password protected computer and file, with access restricted to limited study personnel. Your records may be reviewed by the UC San Diego Institutional Review Board, the University of Colorado Boulder Institutional Review Board, and the people who support this study at the National Institute of Health (NIH).

All results of your assessments (e.g., all of the responses to questions or tasks, scores, MRI results, biological samples, genetic information, DNA, or physiological measures) will be identified only by a unique participant code that contains no explicit information about your identity. Only the research team will have the information that matches the code to traditionally used identifying information, such as name, address, and phone number. Dr. Banich, Dr. Friedman, their her collaborators, and the National Institutes of Health, will keep the information that matches the code to this commonly used identifying information in a securely protected database for as long as the study continues, and then it will be destroyed. Only very few authorized people, who have agreed to protect your identity, will have access to this information that matches your personal information to the anonymous code.

In the coded form, the data will be entered into a database. This database will be accessible to the ABCD study researchers, and the data will also be placed in data repositories maintained or sponsored by the National Institutes of Health. The database will be made available broadly for research and development of new methods. This information may ultimately also have significant therapeutic or commercial value. By agreeing to participate in this study, you agree to such future uses. Individuals who request access to your data will have to agree not to try to identify any individuals who have participated in the study. However, there is a small possibility that in the future an unauthorized attempt to identify you as a participant in the study could succeed.

To help us protect your privacy, Dr. Banich, Dr. Friedman, and the ABCD Investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the research team cannot be forced (for example by court order) to share research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Sharing may be necessary if the DHHS does a review of the study. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If an insurer, employer, or other person obtains your written permission to receive research information, then the researchers may not use the Certificate to withhold that information. If you request that any study data be released to your doctor, this information may then become part of your medical record. Insurance companies may have access to such records. This might then hurt your access to

health or other insurance. However, we will not release information about you to your doctor without your permission.

Finally, you should know the research team can take steps, such as telling authorities (for example, the Police) if 1) you tell us of plans to hurt yourself, 2) you tell us of plans to hurt another person, or 3) we learn that a child or elder has been or is being abused. If you decide at a later time that you do not want your data or specimens to be used for future research, you may tell this to Dr. Banich or Dr. Friedman, who will use their best efforts to prevent use of the data in additional studies. However, it will not be possible to locate and stop such future research once the materials have been widely shared with other researchers.

What risks are associated with this study?

Participation in this study may involve risks or discomforts. These include the following:

1. It is possible you may become tired, bored, or frustrated during the study sessions. You can take a break and/or stop the testing at any time.
2. It is possible that being asked about feelings, mood, traumatic life experiences, or about experiences with alcohol, tobacco, or drugs may make you feel uncomfortable. You will not have to answer questions that make you feel uncomfortable.
3. There is risk of possible loss of confidentiality. The study will be conducted under a Certificate of Confidentiality, and we will make all efforts to keep the information secure. However, there is still a small chance that the information could be discovered and have unknown outcomes.
4. Your biological samples (e.g. saliva, hair, breath) may be tested for use of tobacco, alcohol, and drugs. This testing is necessary to make sure study procedures are appropriate. This testing may show that you have used these substances, but this will not be shared with others. Efforts will be made to keep this information confidential. The drug tests are not labeled with any identifying information. Although the chance this can happen is small, it is possible that others could become aware of a positive substance test.
5. Blood Draw: You may feel brief pain, get a bruise, feel dizzy, or faint during the blood draw. You may have the option of using a numbing cream or spray to reduce discomfort but could have redness or itching and a numb feeling from the spray. You can choose to not do the blood draw.
6. <u>Risks associated with MRI</u>:
   a) The magnetic resonance scanner is a long narrow tube that is open on both ends. Some people get uncomfortable or anxious once inside. You will be able to pause or stop the study and ask questions at any time.
   b) The scanner makes loud banging noises while taking pictures. You will be given earplugs and headphones to help reduce the noise.
   c) There are no known biological or reproductive risks from MRI scans. The procedure does not use radiation, like X-rays. However, because the MRI has a strong magnetic field it is not safe to be in or around the scanner if you have certain implanted metal devices. We will make sure it is safe for you by asking you about any possible metal using a screening questionnaire both before scheduling the scan and again before entering the scanner.
   d) While in the scanner, you may experience a small twitching sensation. This is not unexpected but you should tell the researchers about it right away and we will stop the scan. You might also be dizzy after laying down for a long time. We will help you get up.

e) For females, although there are no known risks of an MRI during pregnancy, if you are pregnant, we will not perform the MRI. You may be given a urine pregnancy test before going into the MRI.

f) Although the MRI is not a diagnostic MRI, all scans will be reviewed by a radiologist and it is possible we may detect an unexpected finding in the brain. This may be distressing to you. The unexpected findings will be discussed with you.

7. Activity tracker (Fitbit). It is possible that you may be uncomfortable wearing the Fitbit. You will be given instructions on how to wear the Fitbit and study staff will be present to make adjustments before you go home. You do not have to wear this.

8. Additional Psychological or Social Risks Associated with Loss of Privacy

While we believe that the risks to you are very low, we are unable to tell you exactly what all of the risks are. Below are some potential risks:

- Your privacy is very important to us and we will use many safety measures to protect this privacy. However, even with all the safety measures that we use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, some genetic information is shared between other blood relatives. This means, it may be possible that genetic information from them could be used to help identify you. Also, it may be possible genetic information from you could be used to help identify other blood relatives.
- While the controlled-access databases used to share data from this project will not contain information that is traditionally used to identify you, such as your name, address, and telephone number, people may develop ways in the future that would allow someone to link your genetic or medical information in these 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 a blood relative). Individuals who request access to your data will have to agree not to try to identify you or any of your relatives, or to contact you or relatives. However, there is a small possibility that in the future an unauthorized attempt to identify you as a participant in the study could succeed.
- Some genetic variations can help predict future health problems. Patterns of genetic variation can be used by law enforcement agencies to identify a person or their blood relatives.
- Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carries a genetic disease. There also may be other privacy risks that we have not foreseen.

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. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

- This new Federal law ***does not*** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

9. Because this is a research study, there may be some unknown risks that are currently unforeseeable. If there are significant new findings during the course of this research that may influence your willingness to continue participating, we will inform you of these findings.

What benefits can be reasonably expected?
There is no anticipated direct benefit to you from participation in this study. The investigators, however, may learn more about how developing mental functions are related to brain development. Such understanding may lead to greater knowledge about how to prevent behavioral problems, or identify and treat behavioral problems at an early age.

Can you withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide to no longer continue in this study, you may notify Dr. Friedman in writing to Institute for Behavioral Genetics, UCB 447, Boulder, CO 80309-0447, by sending an email to abcd@colorado.edu, or by calling the site at (303) 735-2644.

You will be told if any important new information is found during the course of this study that may affect wanting to continue.

Can you be withdrawn from the study without your permission?
You may be withdrawn from the study if Dr. Banich, Dr. Friedman, or the ABCD investigators believe it is in your best medical interest or if you do not follow the instructions from the study personnel.

Will you be compensated for participating in this study?
You will be compensated for your time participating in the study. If you do not finish a study session, you will be paid $10 for every hour completed.

- Baseline: $100 (MRI)
- Year 2: $50
- Year 3: $100 (MRI)
- Year 4: $60
- Year 5: $150 (MRI)
- Year 6: $75
- Year 7: $175 (MRI)
- Year 8: $100
- Year 9: $200 (MRI)
- Year 10: $125

6-month interviews: $15 each interview. During each MRI session there is a reward task performed where you can earn a little more money. This averages about $20.

If you choose to do the blood draw you will be paid an extra $20

If you choose to wear the Fitbit tracking device you will be compensated with $20 when you return the device and finish the questionnaires.

If you choose to participate in the installation of apps to monitor mobile device usage, you will be compensated an additional $20.

If you opt to not complete the MRI for reasons other than having braces or an incompatible medical device, or living far away from a study site, your compensation will be $75 less.

You will be paid a bonus of $20 if you complete your yearly in-person visit on the originally scheduled appointment date.

Because we sometimes have last minute appointments to fill, we may contact you to ask if you could come in on a day prior to your scheduled one. If you agree, we will pay you an additional $20. That means if we ask to you to move from your originally scheduled time, a $40 bonus payment will be added to your compensation.

The payment will be given as cash, gift card, or as a ClinCard (a reloadable credit card that can be used at stores, online, or for cash at local banks).

If you need transportation to the study appointments, we can provide transportation service. We can give you snacks and/or a meal during longer study appointments.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research you should inform Dr. Friedman at 303-735-2644. The cost for any treatment will be billed to you or your medical or hospital insurance. The University of Colorado has no funds set aside for payment of health care expenses for this study. You may call the University's Institutional Review Board at 303-735-3702 for more information about this.

Who can you call if you have questions?

Marie Banich PhD, Naomi Friedman PhD, and/or a member of their research team has explained this study to you and answered any questions. If there are other questions or research-related problems, now or in the future, contact Dr. Banich or Dr. Friedman at 303-735-2644.

You may contact the University's Institutional Review Board at 303-735-3702 or irbadmin@colorado.edu to inquire about rights as a research subject or to report research-related problems.

Your Signature and Consent
You will receive a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep. You agree to participate.

_____	_____	_____
Name (print)	Signature	Date

_____	_____
Signature of Person Obtaining Informed Consent	Date

Check the box below if you <u>do not give permission</u> to be contacted.

☐ NO, I do not wish to be contacted about other studies.