University of Colorado Boulder

Adult Consent to Act as a Research Subject

The Adolescent Brain Cognitive Development (ABCD) Study

Who is conducting the study, why have you been asked to participate, and what is the approximate number of participants in the study?

Dr. Marie Banich, Dr. Naomi Friedman, and the Adolescent Brain Cognitive Development (ABCD) investigators are conducting a research study to learn more about developing cognitive, social, and emotional functions in children as they grow from age 9 to young adulthood. You have been asked to participate in this study because you are the parent, legal guardian, or primary caretaker of a child who is also participating in this study and was age 9 or 10 at the time of their first visit. This same research study is being done at many other research programs across the U.S. This will be the largest study of its kind to date, enrolling about 12,000 healthy children at all locations. There are approximately 550 participating children in Colorado.

Why is this study being done?

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 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. In particular, they will try to identify which factors seem to promote better outcomes, including independence and emotional well-being; and factors that may increase a young person's risk for a negative outcome, such as unhealthy habits and behaviors. The results of this study may help in designing new interventions that prevent negative and increase positive outcomes in young people's lives.

What are the study procedures?

If you agree to participate in this study, you will be asked to complete a set of "baseline" assessments and then will be asked to complete additional assessments on a number of occasions for as long as 10 years.

- We may ask you to provide information including 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 studies. Relatives and friends are told only that this is a study of child cognitive and brain development and no other information about the study or about you is given.
- We will interview you and give you questionnaires on a computer including questions about your mental and medical history, behaviors, experiences with alcohol, tobacco, or drugs, your personality, relationships with friends and family, and about your education and other activities.
- You will be asked to complete an interview and questionnaires about your child or children, who are participating in this study, including questions about his/her mood, personality, behavior, experiences with alcohol, tobacco, or drugs, relationships with friends and family, and school and other activities. We do not share information you tell us, this helps to keep the privacy needed so we get honest answers.

Follow-up

- About every 3-6 months after completing the baseline study, we will contact you for a brief (15 minute) interview and assessments on the phone and/or computer about the child in this study including questions about his/her health, school and other activities, relationships, experiences with any substances, and your current contact information.
- About every 12 months after completing the baseline study, we will ask you to participate in the study again to do the interview and questionnaires.

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

It will take you up to 4-4.5 hours to complete the full study at baseline. In addition, every 12 months, the interview and questionnaires will take the same amount of time or less. The table below shows how much time the study procedures will take, including the brief interviews every 3-6 months (up to 45 minutes total each year). The study is expected to go on for 10 years.

Baseline	Year 2	Year 3	Year 4	Year 5	Year 6	Year7	Year 8	Year 9	Year 10
4-4.5 hrs	2 hrs	4-4.5 hrs	2 hrs	3-3.5 hrs	1.5 hrs	3-3.5 hrs	1.5 hrs	2-2.5 hrs	1 hr

After contacting you to schedule you and your child's next visit, we may send you some forms in advance to be completed at your own leisure via a secure link, if you are interested. This is optional, and if you prefer, you can complete these forms during the in-person visit.

What about your confidentiality?

Research records will be kept confidential. This means what you tell us is not shared outside of the ABCD investigators and study team. Your records with your name and contact information will be stored separately from data collected from you in 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, 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 the interview and questionnaires) will be identified only by a unique participant code that contains no information about your identity. Only the research team will have the information that matches the anonymous code to traditionally used identifying information, such as your name, address, and phone number. Dr. Banich, Dr. Friedman, and their staff will keep the information that matches the code to this commonly used identifying information in a password protected database for approximately 10 years or as long as the study has funding. 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 anonymous 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. It 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 uses. Researchers who request access to your data will have to agree not to try to identify 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 you. If an insurer, employer, or other person obtains your written consent to release research records 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 consent.

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 really hurt yourself, 2) you tell us of plans to really 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 you do not want your data to be used or shared for future research, please tell this to Dr. Banich or Dr. Friedman, who will use their best efforts to stop any additional use or sharing of your data. However, it will not be possible to prevent such future research use once the data has 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 at any time.
2. It is possible that being asked about feelings, mood, or about experiences with alcohol, tobacco, or drugs may make you feel uncomfortable. In most cases you may skip 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. However, if some of the information collected, such as use of illegal substances, were to become known outside of this research setting, it may place you at risk for criminal or civil liability or may be damaging to your ability to get a job, affect personal reputation, or have otherwise unknown outcomes.
4. 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.

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

   While we believe that the risks to you and your family 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 your privacy. However, even with all the safety measures that will be used, we cannot guarantee that your identity will never become known.
   - 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 name, address, and telephone number, people may develop ways in the future that would allow someone to link your mental health or medical information in these databases back to you. For example, someone could compare information in our databases with information from you (or a family member) in another database and be able to identify you or family members.

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 choose not to participate or withdraw your consent 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. Likewise, you may withdraw your consent to participate at any time without penalty or loss. If you decide to withdraw from the study, you may notify Dr. Friedman in writing to Institute for Behavioral Genetics, UCB 447, Boulder, CO 80309-0447, by writing 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 your wanting to continue.

Can you be withdrawn from the study without your consent?

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: $200
- Year 2: $50
- Year 3: $200
- Year 4: $60
- Year 5: $200
- Year 6: $75
- Year 7: $200
- Year 8: $75
- Year 9: $100
- Year 10: $50

3-6 month interviews: $10 each interview.

If you need transportation to the study appointments, we can provide transportation service.

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?
This form explains the research study. Please read it carefully. Ask questions about anything you do not understand. If you do not have questions now, you may ask later.

Marie Banich, PhD, Naomi Friedman, PhD, and/or a member of their research staff has explained this study to you and answered your questions. If you have other questions or research-related problems, now or in the future, you may reach 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 your rights as a research subject or to report research-related problems.

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

_____	_____	_____
Participant Name (print)	Participant Signature	Date

_____	_____
Signature of Person Obtaining Informed Consent	Date

We may inform you about other studies, check the box below if you <u>do not wish</u> to be contacted.

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