

Permission to Take Part in a Human Research Study

Page 1 of 5

Title of research study: *CoTwins (14-0433)*

Investigators: *Naomi Friedman, Ph.D. University of Colorado*
Scott Vrieze, Ph.D. University of Minnesota

Why am I being invited to take part in a research study?

We invite your family to take part in this research study because you are in the Colorado Twin Registry and the twins are Juniors or Seniors in High School.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Study Coordinator, Amy Ledbetter at 303-492-2016, Scott Vrieze at 612-626-7569, or Naomi Friedman at 303-735-4457.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (303) 735-3702 or irbadmin@colorado.edu if:

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

Why is this research being done?

- To learn about how social relationships, abilities, substance use, and mental health are affected by environmental contexts in young adults by using a mix of old and new research techniques including questionnaires as well as smartphone tools such as logging locations, audio samples, and photographs of one’s environment.
- Doing the study with you, as a twin, is invaluable to further our understanding of the interplay between genetic and environmental influences on these behaviors.

How long will the research last?

- You will participate in this research study for *two years* after today’s session, which will last for about 4 hours, we are asking you to occasionally complete short questionnaires on your smartphone

9 November 2018

IRB Approval Date

or computer, to enable the smartphone app to log locations and record brief audio samples, and take occasional photos. At the end of two years you may stop participating.

- Questionnaires will take different amounts of time for different twins, and in most cases will range from 30 minutes to an hour per month.

How many people will be studied?

About 535 families will be in this research study.

What happens if I say yes, I want to be in this research?

- Your family will travel to our lab for a few hours of tests, interviews, and questionnaires.
- If your family is unable to visit us, we will travel to you and make arrangements to conduct the sessions in another private space.
- The twins will work on thinking ability tests, interviews about their life including different kinds of problems, and completion of questionnaires about personality, substance use and their environment.
- While interviewers are working with the twins, parents will use a computer we provide to complete a questionnaire covering similar topics.
- If one parent cannot participate at the in-person session, he or she may complete the questionnaire on-line from home.
- We will collect a saliva (spit) sample from each twin and parents for later DNA studies.
- For the next 2 years, about once a week, both twins will be asked to answer questions that are shorter versions of the ones at the in-person visit, either by going online or using your smart phones.
- An app will be installed on the twins' smartphones that allows the study team to log the twins' online behavior including things such as sites visited, search terms, content exposure, page visits, Twitter activity including tweets/retweets, app use, data transfer, phone metadata, and location logs. The app is also designed to collect audio samples and will send push notifications for the twins to take photos of their surrounding environment. Members of our team in Minnesota or Colorado may contact you from time to time to make sure the apps are working. At the end of the second year we will send you a reminder that you may at that time un-install the app.
- Audio recordings will be brief recordings (e.g., a few minutes) that will take place multiple times daily. These recordings will be stored on secure servers separately from identifying information, and only select study personnel will have access to them. We will use analysis tools to extract features from these recordings including simple environmental cues, such as whether you were outside, inside, in a social setting, etc. We will work hard to ensure that recordings will only take place when your phone has sufficient battery, and that the recordings themselves will not cause noticeable battery drain. Before the audio recording is transferred to study servers for analysis, we will identify voices in the recording and extract features (e.g., age, male/female, number of voices, and so on), and then "scrub" the voices so they are unrecognizable. In this way, the few select study personnel who have access to the database of recordings will not be able to re-identify anyone in the audio recordings. As phones and analysis tools improve, we may analyze the entire audio recording on the phone and transfer only the extracted features, and none of the original recording, to our servers.
- Each week, you will be prompted by the app to take pictures of your surroundings. At a minimum, we will ask you to take two pictures each week, one when you are at home and one when you are outside your home (e.g., work). These photos will be stored on secure servers separately from identifying information, and only select study personnel will have access to them. As an extra security precaution, we will analyze each image to determine whether the image contains faces. The software will attempt to extract features of those faces (e.g., age, male/female, emotion, and so on), and then "scrub" those faces from the image before the image is stored on our servers. In this way,

the few select study personnel who have access to the database of images will not be able easily to re-identify you or anyone else in the picture.

- At various intervals, we will ask you to complete an on-line version of one of the thinking tests. If you do not have access to a computer on which to complete this task, we may lend one to you. In this case, we would provide you with prepaid postage and packing materials in order to return the computer to us.
- Due to the nature of the software, the CoTwins app will continue to collect data for use in the study beyond the two-year anniversary of your enrollment unless disabled or uninstalled by you. Any additional data will be stored and analyzed in the same way as that data collected during the normal 2-year participation period.
- We may contact you in the future to ask if you want to be in a follow-up to this study or in another study.

What happens if I do not want to be in this research?

- Nothing. You won't be in this research but could still be in other twin studies if you want to.

What happens if I say yes, but I change my mind later?

- You can leave the research at any time and it will not be held against you.

Is there any way being in this study could be bad for me?

- There is a small chance you might be embarrassed about some survey items. If you do find some questions embarrassing, you can contact our study team.
- The main risk is if your answers to the questions (e.g., about illegal activities) or other data became public.
- We have more than 30 years of experience doing studies like this with other families of twins and have excellent systems in place to make sure all of your information is kept confidential. We also have a Certificate of Confidentiality from the National Institutes of Health, which allows us to refuse subpoenas requesting your data.

Will being in this study help me in any way?

- We cannot promise any benefits to you or others from your taking part in this research.
BUT--
- This study may be important because young adults are at particular risk for substance misuse and dependence, and it is well-known that environmental stressors and influences contribute to substance use. This study will investigate new ways to measure and evaluate the influence of such stressors.
- This study might help us better understand how teenagers use online media.

What happens to the information collected for the research?

- We will make every effort to maintain the privacy of your data.
- ***No family member will be able to find out what other family members do or say.***
- Everything we collect will be identified only by a ***numerical code, not names.***
- All written materials are stored in locked rooms in locked file cabinets.
- The DNA sample is stored only by an anonymous lab number in a different locked room.
- All in-person materials are stored in password-protected electronic files.
- The link between your name and the in-person information about you can only be accessed by a limited number of people—the study coordinator and data managers.
- Some information, like the questionnaires, will be direct but some of it will be indirect. We will have programs working “behind the scenes” that will record information about your activity—what sites

you visit, what you post, tweet, etc., where you go and the attributes of the places you spend your time.

- In order to gather this information, we have created a smartphone app that we will ask you to install on your phone.
- The information collected by the app will be uploaded to a secure cloud server.
- The information about your activity will be stored using the random code in one place within this database whereas your email address, name, and other contact information, will be stored in a different place within this database. Only select study personnel will be able to access both places in this database.
- If the study comes to a complete end, we will purge directly identifying information about you from both places. The researchers will safely store all of your responses and other data indefinitely. However, you may have your information, including the DNA sample, removed from future analyses by sending a letter to the research team requesting that it be removed.
- ***In addition, a Certificate of Confidentiality has been obtained from the National Institutes of Health. This certificate will protect the investigators from being forced to release any research data in which you are identified even under a court order or lawful subpoena.***
- However, you may still voluntarily request that your own data be released.
- Further, authorized personnel from the funding agency at the National Institute of Health may request information only as needed to evaluate the progress of the research to protect against fraud in federal research programs. The exception to the promise of confidentiality is that if information is revealed concerning abuse or neglect of a child or at-risk adult, or potentially dangerous future behavior involving a serious threat of imminent physical violence against a specified person or persons, we will report this to the proper authorities. Other than the research team, only regulatory agencies such as the Office of Human Research Protections and the University of Colorado Institutional Review Board, and NIH may see your individual data as part of routine audits.
- We may share your data with scientists from other institutions. When we share data we will not include your names, addresses, e-mail information, or other contact information. We will not share other information that is potentially identifying, such as location, audio samples, or photos, unless the other institution provides proof of standard ethical review and approval, and signs a data use agreement where they promise not to identify participants.

What else do I need to know?

Who funds the project?

- This study is being funded by the National Institutes of Health, a federal agency that requires that data be collected in a form that may be analyzed for differences between men and women and races or ethnic groups.

Will I be paid?

- Each family will be paid a total of **\$900** for completing the full 2 years of the study.
 - Twins will be paid \$100 each in cash at completion of the in-person session.
 - During the 2 year follow-up, payments will be made to each twin by check in increments of \$100 every 8 months.
 - Parents will be paid \$50 for completion of the questionnaire, by cash if in-person, by check if on-line.
 - For incomplete participation of the follow-up, we may pay \$5 per month.
 - If you travel to our facility for the in-person session, you will also receive reimbursement for your travel costs, locally at the current CU-Boulder mileage rate and distantly at the state authorized travel rates.
- Each twin will receive a T-shirt.

Your signature documents your permission to take part in this research.

Signature Block for Mother/Legal Guardian

Signature of subject	Date
Printed name of subject	

Signature Block for Father/Legal Guardian

Signature of subject	Date
Printed name of subject	

Signature Block for Twin 1

Signature of subject	Date
Printed name of subject	

Signature of Parent/Legal Guardian

Signature Block for Twin 2

Signature of subject	Date
Printed name of subject	

Signature of Parent/Legal Guardian

The IRB determined that the permission of one parent is sufficient. **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise.

Signature of person obtaining consent and assent	Date
Printed name of person obtaining consent and assent	9 November 2018
	IRB Approval Date