

## PAPERWORK REDUCTION ACT STATEMENT

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## MODERATOR'S GUIDE

### HOUSEKEEPING

*Please note: Participants have been asked to log in 5 to 10 minutes prior to the start of the discussion. During this time, the moderator will ensure that each participant can see the shared screen, is in a private space with no other individuals present, and knows how to mute their microphone when not speaking.*

Before we begin, I just want to make sure that you're able to see the shared screen and are able to minimize background noise (either by using headphones or being in a quiet room).

Good [evening/afternoon]. Thank you for taking the time to participate in this discussion. My name is [XXXX], and I am going to facilitate our conversation.

A few housekeeping items to review:

- We will use the findings from today's discussion only to inform the development of questions asked in the Adolescent Brain Cognitive Development<sup>SM</sup> Study, also called the ABCD Study<sup>®</sup>.
- Please put your smartphone or tablet on Do Not Disturb mode while we are in this discussion. I want to make the most of our time together.

In terms of your feedback:

- There are no right or wrong answers to any of the questions I will be asking. Please be honest.
- If something feels uncomfortable or unclear, we want to know. Please don't worry about being polite, or holding back. I didn't write any of the questions we're going to be looking at together.
- You are not required to answer every question. You can "pass" if any question makes you uncomfortable. You are also free to stop participating at any time.

## BACKGROUND

- I am a trained moderator with IQ Solutions, a company that is holding these discussions to help the National Institute on Drug Abuse (or NIDA).

- NIDA manages the Adolescent Brain Cognitive Development (ABCD) Study—the largest long-term study of brain development and child health in the United States.
- We're looking for your feedback on some materials the Study uses to give people an idea of research activities related that are part of the ABCD Study.
- We want to make sure any questions/instructions don't leave anyone confused, uncomfortable, offended, or feeling like their experiences aren't included.
- Our discussion will be recorded so that I can refer to the recording as needed for my report writing, and my colleague is also on the line to take notes. In addition, other project staff are on the line listening to today's discussion. **Are you okay with this discussion being recorded? [Notetaker to press "record" if participant consents.]**

## INTRODUCTION

For our first question:

1. What is one thing you are looking forward to this [season]?

## FEEDBACK ON STUDY MATERIALS

Now I'm going to switch topics a bit. Before this discussion, we asked you to look at some materials or instructions that will be used in the ABCD Study later this year.

### What are EHRs?

Health records are the information collected about you when you get health care. They include information about the care you get. Electronic health records, or EHRs, are when this information is kept in secure electronic systems.

### Why is this study being done?

Your EHRs contain important information about your health. They are a way for researchers to get a picture of your health over a long period of time.

We will add your EHRs to your ABCD Study data we have already collected. This will allow researchers to use these health records alongside your other ABCD Study data to better understand adolescent and young adult development. Information from your record will be part of the ABCD Study database. Information that directly identifies you, like your name or address, will **not** be part of this database, like with the rest of your ABCD data. Before researchers will be allowed to see your data, they will have to sign a contract agreeing they will not try to find out who you are. This contract also says how they can and cannot use your data. Researchers will use this database to make discoveries about health. You can learn more about the research being done at <https://abcdstudy.org/publications/>.

2. What did you find surprising on this page?

3. How would you summarize this page in your own words?
4. What questions do you have after reading this page?

### **What is in my EHRs?**

The information in your EHRs depends on what kinds of health care providers you see. Your EHRs tell about any health problems you have seen a health care provider about. They tell about care you have received. They may list the medicines you take. They may have laboratory/test results. They may have images, like X-rays. If you have had a medical procedure, notes about it will likely be in your EHRs. Any time you see or have any interaction with a health care provider that uses EHRs, a note is created.

Your EHRs may also tell how much you were billed and how much you paid for your care.

### **Is there sensitive information in my EHRs?**

There may be sensitive information in your EHRs. For example, there may be information about your use of alcohol or drugs. Or about tests and treatments for sexually transmitted infections, like HIV. They may have results from genetic (DNA) tests. We will be able to see this information.

If you have seen healthcare providers such as doctors, nurses, social workers, medical technicians or counselors, information about your diagnosis and treatment may be in your EHRs. For example, if you have seen counselors or doctors who treat

- addictions (also known as substance use disorders);
- mental health conditions, like depression or bipolar disorder; or
- trauma, from things like domestic violence and sexual assault.

5. What did you find surprising on this page?
6. How would you summarize this page in your own words?
7. What questions do you have after reading this page?

**How will my confidentiality and privacy be protected? Is there anyone else who will see my EHRs?**

Like with the rest of your ABCD Study data, we will add your EHRs to the ABCD Study data resource that is broadly available to researchers. It will not include your name or other information that directly identifies you, like your address or other identifiers. Access to this database is strictly controlled. Before researchers will be allowed to access the data, they will have to sign a contract agreeing they will not try to find out who you or other participants are. This contract also says how they can and cannot use your data. These researchers may be from anywhere in the world. They may work for commercial companies, like drug companies. Their research may be on nearly any topic.

Your information may no longer be protected by patient privacy rules (like "HIPAA") once you share it with ABCD. This is because ABCD does not provide medical care. The patient privacy rules that apply to health care providers do not apply to ABCD. The copies of your EHRs that are with your health care providers will still be covered by HIPAA. The copies that are shared with ABCD will be protected by other privacy rules and agreements like those described in this consent form and your main ABCD Study consent form. These include the rules and agreements that researchers must follow to use the ABCD Study database.

8. What did you find surprising on this page?
9. How would you summarize this page in your own words?
10. What questions do you have after reading this page?

**What if I don't want ABCD to have my EHRs? What if I change my mind?**

Sharing your EHRs with ABCD is voluntary. You get to choose. No matter what you decide, it will not affect your medical care. It will not affect your treatment, payment, enrollment, or eligibility for any health care benefits. It will not affect your ability to continue in the ABCD Study.

If you decide to authorize ABCD to get your EHRs, you can change your mind at any time. If you decide you want to stop allowing us to get this information, you need to tell us. You can use the contact information at the end of this form to call or write to us.

If you tell us to, we will stop getting your EHRs. Data from your EHRs will not be used for new studies. But, if researchers have already used data from your EHRs for their studies, ABCD cannot get it back. Also, we will let researchers check the results of past studies. If they need your old data to do this work, it will be given to them.

11. What did you find surprising on this page?

12. How would you summarize this page in your own words?

13. What questions do you have after reading this page?

*[Stimulus Description:]* Now I would like to ask about sharing your family medical history. Before this discussion, we asked you to look at an example medical history form.

14. First, can you tell me about a time when you had to provide a medical history for your child. What was that experience like? What was easy? What was hard? Were there any questions you couldn't answer?

15. What areas of the family history form did you circle/highlight or take a note as potentially confusing or harder to fill out, and why? If you didn't identify any areas like that, tell me more about that, too.

## CONCLUSION AND OBSERVER QUESTIONS

I have one last question:

16. What is one thing you read or heard about in this discussion that was new to you?

Now I'd like to ask the observers if they have any additional questions or need clarification on any of the issues we've discussed. *[Moderator will review any questions from observers via a private communication channel and pose those to the participants, as time allows.]*

Thank you so much for taking the time today to discuss these topics with me. The sponsors of this project appreciate your honest feedback and reactions.