

## PAPERWORK REDUCTION ACT STATEMENT

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## Instructions

Thank you for being part of our feedback team! We understand your time is important, so we want you to read through the materials before your scheduled interview, to make the most of the discussion time. Please read over the following visuals to get familiar with them before your session.

As you read, please circle/highlight or take notes on anything in the slides that is confusing or that you have questions about. (You can do this on a print-out, in this electronic document, or in a separate note or scratch paper.) For pages with questions, we do not need to know what your answers to those question would be. Instead, we are interested in your feedback on how those questions are written.

Please have your circles/highlights or notes ready during the discussion. We look forward to hearing your feedback during your scheduled interview!

## Draft EHR Consent Form

### 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/>.

### **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.

We **will** be able to see this information.

### **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.

### **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.

## **Draft Family History Form**

### **Personal and Family Health History**

The following questions will ask about your youth's family medical history. This includes conditions that your youth, the youth's biological parents, siblings, grandparents, aunts and uncles currently have or have ever experienced in the past.

When referring to family, please only consider biologically-related relatives.

How much do you know about your family's health history, including health problems for your parents, grandparents, siblings and/or children?

- A lot
- A little
- None at all

The following survey will be organized by type of condition. Please answer about only yourself and biological relatives to the best of your knowledge.

**Cancer Conditions**

Has anyone in your youth's family ever been diagnosed with a cancer condition?

If yes, which of the following cancer conditions has a member of your youth's family been diagnosed with?

1. Bladder cancer
2. Blood or soft tissue cancer
3. Bone cancer
4. Brain cancer
5. Breast cancer
6. Colon cancer/rectal cancer
7. Endocrine cancer
8. Endometrial cancer
9. Esophageal cancer
10. Eye cancer
11. Head and neck cancer (including cancers of the mouth, sinuses, nose or throat. This does not include brain cancer)
12. Kidney cancer
13. Lung cancer
14. Ovarian cancer
15. Pancreatic cancer
16. Prostate cancer
17. Skin cancer
18. Stomach cancer
19. Thyroid cancer
20. Other cancer

**Heart and Blood Conditions**

Has anyone in your youth's family ever been diagnosed with a heart or blood condition?

If yes: Which of the following heart and blood conditions has a member of your youth's family been diagnosed with?

1. Anemia
2. Aortic aneurysm
3. Atrial fibrillation (a-fib) or atrial flutter (a-flutter)
4. Bleeding disorder
5. Congestive heart failure
6. Coronary artery/coronary heart disease (includes angina)
7. Heart attack
8. Heart valve disease
9. High blood pressure (hypertension)
10. High cholesterol
11. Peripheral vascular disease
12. Pulmonary embolism or deep vein thrombosis (DVT)
13. Sickle cell disease
14. Stroke
15. Sudden death
16. Transient ischemic attacks (TIAs or "mini-strokes")
17. Other heart or blood condition

**Digestive Conditions**

Has anyone in your family ever been diagnosed with the following digestive conditions?

1. Acid reflux
2. Celiac disease
3. Colon polyps
4. Chron's disease
5. Diverticulitis/diverticulosis
6. Gall stones
7. Irritable bowel syndrome (IBS)
8. Liver condition (e.g., cirrhosis)
9. Pancreatitis
10. Peptic (stomach) ulcers
11. Ulcerative colitis
12. Other digestive condition

**Hormone and Endocrine Conditions**

Has anyone in your youth's family ever been diagnosed with a hormone and endocrine condition?

If yes: Which of the following hormone and endocrine conditions has a member of your youth's family been diagnosed with?

1. Hyperthyroidism
2. Hypothyroidism
3. Prediabetes
4. Type 1 diabetes
5. Type 2 diabetes
6. Other hormone/endocrine condition

**Kidney Conditions**

Has anyone in your youth's family ever been diagnosed with a kidney condition?

If yes: Which of the following kidney conditions has a member of your youth's family been diagnosed with?

1. Acute kidney disease with no current dialysis
2. Kidney disease with dialysis
3. Kidney disease without dialysis
4. Kidney stones
5. Other kidney condition

**Lung Conditions**

Has anyone in your youth's family ever been diagnosed with a lung condition?

If yes: Which of the following lung conditions has a member of your youth's family been diagnosed with?

1. Asthma
2. Chronic lung disease (COPD, emphysema, or bronchitis)
3. Sleep apnea
4. Other lung condition

**Brain and Nervous System Conditions**

Has anyone in your youth's family ever been diagnosed with a brain and nervous system condition?

If yes: Which of the following brain and nervous system conditions has a member of your youth's family been diagnosed with?

1. Cerebral palsy
2. Chronic fatigue
3. Concussion or loss of consciousness
4. Dementia (including Alzheimer's, vascular, etc.)
5. Epilepsy or seizure
6. Lou Gehrig's disease/Amyotrophic Lateral Sclerosis (ALS)
7. Memory loss or impairment
8. Migraine headaches
9. Multiple Sclerosis (MS)
10. Muscular dystrophy (MD)
11. Neuropathy
12. Parkinson's disease
13. Restless leg syndrome
14. Spinal cord injury or impairment
15. Traumatic brain injury (TBI)
16. Other brain or nervous system condition

**Bone, Joint, and Muscle Conditions**

Has anyone in your youth's family ever been diagnosed with a bone, joint and muscle condition?

If yes: Which of the following bone, joint and muscle conditions has a member of your youth's family been diagnosed with?

1. Fibromyalgia
2. Gout
3. Osteoarthritis
4. Osteoporosis
5. Pseudogout (CPPD)
6. Rheumatoid arthritis (RA)
7. Systemic lupus
8. Other bone, joint, or muscle condition: \_\_\_\_\_

**Hearing and Eye Conditions**

Has anyone in your youth's family ever been diagnosed with a hearing and eye condition?

If yes: Which of the following hearing and eye conditions has a member of your youth's family been diagnosed with?

1. Cataracts
2. Glaucoma
3. Macular degeneration
4. Severe hearing loss or partial deafness in one or both ears
5. Tinnitus
6. Other hearing or eye condition

**Other Conditions**

Has anyone in your family ever been diagnosed with the following other conditions?

1. Allergies
2. Endometriosis
3. Enlarged prostate
4. Fibroids
5. Polycystic ovarian syndrome (PCOS)
6. Skin condition (e.g. eczema, psoriasis)
7. Other: \_\_\_\_\_